

EVALUATION ON DG ENTERPRISE AND INDUSTRY LEGISLATION –
COSMETICS AND EXPLOSIVES DIRECTIVES

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EUROPEAN COMMISSION

Final Report (Explosives Directive)

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Contact person for this contract:

James Leather, james.leather@ghkint.com

GHK, Heckfield Place, 526-528 Fulham Road

London SW6 5NR

Tel: +44 (0)20 7471 8000

Fax: +44 (0)20 7736 0784

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EXECUTIVE SUMMARY

This evaluation

EEC (GHK and Technopolis) was commissioned by DG Enterprise and Industry to carry out an evaluation of the Explosives Directive. This report presents the findings of this study.

The aim of the evaluation was to assess the effectiveness, impact and utility of the Explosives Directive, in terms of the Single Market and safety and security in the explosives industry. This work involved the completion of a number of research tasks:

- § A desk-based review of the available evidence, reviewing the operation of the Explosives Directive, exploring the nature of the explosives industry and how it has changed since 1993;
- § Compilation of an intervention logic for the Directive, setting out how it is supposed to operate and its anticipated outcomes and impacts;
- § A survey sent to 26 Competent Authorities, exploring how the Directive is implemented, and its effectiveness, impact and utility;
- § Detailed case studies of the operation of the Explosives Directive in six Member States: France, Germany, Italy, the Netherlands, Spain and the UK;
- § A survey of explosives businesses.

The Explosives Directive

Council Directive 93/15/EEC (the Explosives Directive) was adopted in 1993 in order to regulate the civil explosives market in Europe. The primary purpose of the Directive was to develop a Single Market in explosives through the harmonisation of product safety standards that, at the time, varied substantially between Member States. These safety standards were set at a high level of protection, and through these the Directive has also contributed towards improving safety in the industry. Finally, the Directive also aimed to enhance security in the industry, primarily through improved supervision during the transfer of explosives, and better information sharing between Member States.

Key elements of the Explosives Directive include:

- § A set of essential safety requirements that must be met by explosives products if they are to be sold on the EU market, incorporating standards in respect of product stability, resistance to temperature, sensitivity etc. The technical details of these standards are drawn up by the European Committee for Standardisation (CEN), and are not included in the text of the Directive;
- § To ensure that they meet these requirements, products must undergo a conformity assessment test, carried out by a registered Notified Body. Notified Bodies are independent third party organisations that are assessed and approved by the authorities in their Member State; most are public laboratories;
- § A product that has passed the requisite conformity assessment is entitled to make use of the CE marking. This marking is mandatory for sale in the EU

market, and Member States cannot prevent such a product from entering their national market;

- § The Intra-Community Transfer of Explosives (ICTE) document within the Directive harmonises the paperwork required during the cross-border transportation of explosives products.

Evaluation results

The problems that the Explosives Directive was designed to address

The primary reason for the introduction of the Explosives Directive in 1993 was to facilitate the development of a Single Market in explosives. Unfortunately there are no data on trade as far back as 1993. Since 1999 the volume of intra-Community trade in explosives has fluctuated, though the overall trend is of a slight increase. Businesses surveyed as part of the study indicated that, on average, the EU market currently constitutes 15% of their total sales, up from around 9% in 1993. The global market has also become increasingly important to EU firms (currently 16% of sales compared to 4% in 1993).

The Directive was also intended to improve safety in the industry. Historical EU-wide data on explosives accidents are not available, and so it is not possible to provide a comprehensive account of the scale of the problem. However, a review of the available information – consultation with Member States, a review of the MARS database of major industrial accidents – has not identified a single case where a finished explosive has malfunctioned and caused an accident. Where accidents have occurred – and there have been a number of serious incidents at explosives manufacturing plants involving fatalities – it has always been a result of human error or plant equipment failure.

The Directive was also intended to contribute towards enhancing security in the explosives industry. Data on security breaches are hard to obtain since Member States are reluctant to put such information into the public domain. Consultation with Member States has revealed that there have been cases since 1993 where terrorists or criminals have stolen explosives, but that these events are very rare, and so it is difficult to determine any trends since the Directive was introduced.

The application and implementation of the Explosives Directive

The conformity assessments are the critical aspect of the Explosives Directive, ensuring that products are safe and also enabling the operation of the CE marking system that underpins the Single Market. On average businesses reported that they undertake a total of 14 conformity assessments each year. Their choice of which Notified Body to use is dependent on a range of factors, including: the time taken by the Notified Body to complete the process; the associated cost; the proximity of the Notified Body to the site of manufacture; and the quality of the testing process. Costs do vary between the Notified Bodies, but on average each conformity assessment costs €5,000. The average annual costs per business was €77,000, though for individual firms this could range from €10,000 to €300,000, depending on the number of new products being developed.

There is evidence that Notified Bodies do not approach the conformity assessments in a consistent manner, and that this has implications for the functioning of the Single Market. The key issue is the place of manufacturers' tests in the conformity

assessments. A minority of Notified Bodies – most notably the HSL in the UK, but also INERIS in France – are willing to make use of these tests, whilst the majority of Notified Bodies refuse to do so on the grounds that the conformity assessment process should be completely independent, and manufacturers' tests cannot always be relied upon (each year a small proportion of products submitted by businesses – 5% in 2006 – fail the conformity assessments). It is possible that the inconsistency that this creates has contributed to the claim by a number of businesses – denied by all of the Member States consulted – that on occasions the authorities have not accepted the validity of a CE marked product, despite this being in violation of the Directive.

Notified Bodies were initially assessed to ensure that they were able to carry out the conformity assessments, either by their national Competent Authority or another accreditation body. Member States are also responsible for ongoing quality control to ensure that Notified Bodies remain capable, yet it is clear that this is not happening systematically in many countries. In part this is due to the high level of technical expertise required to assess the activities of the Notified Bodies. Alongside formal monitoring there is also a system of informal quality control between the Notified Bodies, based on twice yearly meetings and regular communication between the individuals involved. Consultees were confident that such mechanisms would be sufficient to ensure that any problems with a Notified Body would be identified.

Member States are responsible for ensuring that products on their national market comply with the requirements of the Explosives Directive, primarily through in-market surveillance. The Directive does not specify how this should be done, and consequently there are some variations in the approaches adopted by the Member States. Most authorities are relatively thorough with regard to in-market surveillance, carrying out checks as part of inspections at facilities where explosives are manufactured, stored or used. In France, for instance, 12 premises are inspected at random each year to ensure that all products comply with the Directive. Member States report that there is almost universal compliance; since 1993 there have only been three cases where explosives have been discovered without a CE marking.

The ICTE form was introduced by the Commission in 2004 in order to harmonise the paperwork required during the internal cross-border transportation of explosives. Consultees from Member States and businesses were generally in agreement that the ICTE form is working well, and constitutes a significant improvement on previous arrangements (when forms would have to have been obtained from each authority along the route of transportation, and may have varied in content). However, the ICTE document must still be completed and returned in paper form, which costs money (generally between €30 and €50 per form) and causes delays. Of the ten businesses that replied to the survey, five thought that the costs of the ICTE form were 'too high'.

The effectiveness and impact of the Explosives Directive

The primary aim of the Directive was to develop a Single Market in explosives products through the creation of a harmonised set of safety tests. In general this system is working effectively, though consultees – businesses and Competent Authorities – reported a number of operational problems. Of the ten businesses who responded to the survey, all reported that they still experienced barriers to trade, of which the most common were regulatory hurdles (mentioned by 80% of respondents). A number of firms indicated that a small number of Member States do not always accept the validity of a CE marked product, and order a retest before the product can be sold on their

market (this is in violation of the Directive). In other cases firms reported that administrative requirements specific to Italy and Spain caused delays and increased the costs of exporting products to both countries. In the case of Italy, the authorities insist that products must be accompanied by the full report of the conformity assessment, translated into Italian.

The majority of Competent Authorities – 83% of survey respondents – felt that there were no remaining barriers to trade, highlighting the difference in opinion between businesses and the regulatory authorities. Two Member States noted that they were aware that not all authorities always accepted the validity of CE marked products. On a related note, Competent Authorities were surveyed regarding the impact of the Explosives Directive on intra-Community trade. Opinion was split, with 44% reporting a 'positive impact', and 39% arguing that the Directive had had 'no impact'. Two of the recent accession states reported a noticeable increase in the volume of non-domestic explosives available on the national market.

The Explosives Directive was also intended to improve safety in the industry through the creation of a harmonised set of product safety standards. As part of the survey, Member States were asked whether the Directive was effective in improving safety, and the majority reported that this was the case during product manufacture (72% of respondents) and use (61% of respondents). Regarding transportation the proportion was just 22%, with respondents noting that other legislation in this area – such as the ADR – was more influential. National legislation is particularly important regarding safety in the industry since the safety tests in the Directive only ensure that the finished product is safe. Analysis of accident data indicates that all of the major incidents since 1993 were the result of human error or equipment malfunction, neither of which is affected by the Directive.

Security is similar in that the Directive has very little control in this area, except in relation to enhanced and standardised supervision of cross-border movements of explosives, and arrangements for information sharing between Member States. This was reflected in the survey responses of Member States, with 45% reporting that the Directive is effective in improving security, and the majority indicating that the Directive had had 'no impact' on security in the industry. Nevertheless, there have been a number of cases where explosives have been stolen in the past few years, and it is clear that there is a wide variation between Member States regarding national security standards. Since this is very much an EU-wide issue, there was support amongst consultees for the creation of EU-wide minimum security standards.

The utility of the Explosives Directive

Competent Authorities in the Member States were surveyed and consulted to determine whether they felt that the Explosives Directive remains fit for purpose. The majority (61%) indicated that they were content with the present form of the Directive. Some 33% of Competent Authorities argued that changes were needed, including: the introduction of an online ICTE form; the development of harmonised security standards; specific consideration of the usage of explosives in the Directive; the usage of the CE marking on trucks transporting bulk explosives; and, an identification number of Notified Bodies rather than an identification symbol.

Businesses were also asked to indicate whether they would like to see any changes to the Explosives Directive. Responses were similar, and included: extension of the

Directive to cover the usage of explosives; improved clarity regarding the conformity assessments; an interactive online version of the ICTE form; and a simplification of administrative requirements in certain Member States.

Conclusions and recommendations

Conclusions have been organised around the evaluation research questions:

- § *How is the Explosives Directive implemented in the Member States?* The critical aspect of the Directive is the way in which Member States and Notified Bodies approach the conformity assessments. Evidence suggests that the implementation of this system is not operating quite as anticipated, and that there are important differences between Notified Bodies in how the conformity assessments are carried out (primarily in relation to the role of manufacturers' tests). Competent Authorities are supposed to monitor the Notified Bodies to ensure that they remain able to carry out the conformity assessments, yet evidence suggests that this is not taking place systematically across all Member States, though there is an informal network of quality assurance operating between the Notified Bodies. Member States also have responsibility for ensuring that all products on their national markets comply with the requirements of the Directive. Most Member States implement fairly comprehensive programmes of random inspections of sites where explosives are manufactured, stored or used, and consultees could only identify three instances where non-compliant products had been discovered. Finally, in 2004 the ICTE form was introduced in order to harmonise the paperwork required during the internal cross-border transportation of explosives. The form seems to be universally accepted by Competent Authorities, and the only problems relate to the associated administrative costs.
- § *What are the barriers to the effective application of the Directive?* The effective application of the Directive is affected by the differences in the way that Member States approach its implementation. The key issue relates to the conformity assessments, though there are also some differences in how Member States carry out in-market surveillance and how they monitor the quality of the Notified Bodies. The most important barrier to the effective application of the Directive, however, is external, and concerns the way in which the Directive fits with varying national legislation. National legislation governs safety and security in the industry, though in some cases laws brought in to regulate these areas also infringe on the operation of the Single Market (particularly in respect of the administrative costs of compliance).
- § *What are the strengths and weaknesses of the Directive and which parts have been more or less effective?* As the table overleaf indicates, the strengths of the Directive are: its introduction of a set of harmonised safety standards that have removed a key barrier to trade; the use of the CE marking and the almost universal compliance; the introduction of the ICTE form; and the flexibility achieved through using CEN to define the technical standards. Weaknesses include: a lack of detail regarding the conformity assessments that has enabled variations in approaches between Notified Bodies; a focus on Single Market issues rather than safety and security in the industry; and the fact that the ICTE form cannot be completed electronically. Overall, the parts of the Directive designed to facilitate the development of a Single Market are operating reasonably effectively, though there are some operational problems that need to be resolved. Safety and security are largely regulated by national legislation,

and thus the effectiveness of the Directive is impossible to judge. Overall the explosives industry is relatively safe, and in fact safety standards do not vary significantly between Member States. Security is another matter – national standards are very different, and there have been a number of instances in the past few years where explosives have been stolen. Since this is an EU-wide issue, there is support amongst Member States for the creation of minimum EU-wide security standards.

- § *Has the Directive contributed towards the development of a Single Market?* The limited evidence available suggests that there has been steady progress made towards the development of a Single Market, and firms report that a growing proportion of their income is derived from non-national European sales. However, it could also be argued that progress towards the Single Market has not been as rapid or as wide-ranging as might be expected – businesses still derive the majority of their income from their respective national markets. There is evidence that there are still a number of trade barriers in place, in particular the issue of whether or not Competent Authorities always accept the validity of CE marked products. In other cases administrative requirements enforced by certain countries – usually required for national safety or security reasons – also increase the costs of selling explosives products in some EU countries.
- § *What have been the impacts of the Directive on European companies and has it added administrative costs and burdens?* The most significant impact of the Directive on businesses has been the effect it has had on the operation of the Single Market. Firms generate a small but increasing proportion of their income from EU markets, and indeed world markets, and there is a consensus amongst Member States and businesses that this can in part be attributed to the Explosives Directive. There are administrative costs for businesses associated with the Explosives Directive, primarily the cost of the conformity assessments (on average €5,000 per product), and also the ICTE form (on average €30 to €50 per form). Half or more of businesses felt that these costs were too high (60% in respect of the conformity assessments, and 50% in respect of the ICTE form).

Strengths	Weaknesses
<p>Safety tests have been successfully harmonised across the EU, removing a key barrier to trade.</p> <p>The mandatory application of the CE marking has ensured that all products meet these high safety standards. Non-compliance within the industry is almost unheard of.</p> <p>The technical criteria applied during the conformity assessments are determined by CEN, an independent expert body. Flexibility is thus inbuilt, and standards can be changed far quicker than if an amendment to the text of the Directive</p>	<p>There is insufficient clarity regarding the way in which the conformity assessment modules are to be carried out, resulting in variations in approach between the Notified Bodies.</p> <p>The Directive has done little to improve security in the industry, and consequently there are still a wide range of standards in operation across the EU. In addition to making the industry less secure, these variations also affect the operation of the Single Market.</p> <p>Safety also remains a largely national consideration, though the variations in</p>

Strengths	Weaknesses
<p>was required (which would then need to be transposed into 27 Member State laws).</p> <p>The ICTE form has made the intra-Community transport of explosives considerably easier, and reduced costs for businesses. Previously firms had to meet varying national requirements regarding obtaining permission to transport explosives.</p>	<p>minimum standards between Member States are less pronounced than for security. Again, any variations will affect the operation of the Single Market since the costs associated with compliance will vary.</p> <p>The ICTE form is not accessible electronically, and thus has not gone as far as it could in terms of simplifying administrative requirements.</p> <p>The scope of the Directive could be clearer; specifically, whether it only covers products placed on the market (as it does in relation to the Single Market and safety), or extends to products regardless of their status (as it does in relation to security).</p>

Based on the results of the evaluation, the study team makes the following recommendations for improving the utility of the Directive:

- § Working together with CEN, the Notified Bodies and the Competent Authorities, DG Enterprise and Industry should clarify whether manufacturers' tests should be included within the conformity assessment, since the lack of clarification affects the operation of the CE marking system.
- § DG Enterprise and Industry should publish an interactive electronic version of the ICTE form in order to make the process of transferring explosives across internal borders quicker and less expensive for firms.
- § DG Enterprise and Industry should consult with industry stakeholders as to whether the ICTE system is necessary and whether, in its present form, it enhances security.
- § DG Enterprise and Industry should consider whether the Explosives Directive should include a minimum set of security standards since there are presently a broad range of systems in place within the Member States.
- § DG Enterprise and Industry should consider whether administrative requirements in place in some Member States constitute a barrier to trade, and thus whether the Directive should specify the paperwork that should accompany an explosive product when it crosses a border (particularly regarding language).

The conclusions and recommendations of the study team are summarised in the following table:

Conclusion	Recommendation
<p>Whilst the Explosives Directive has been largely successful in removing barriers to trade (such as</p>	<p>Working together with CEN, the Notified Bodies and the Competent</p>

Conclusion	Recommendation
<p>the differing national safety standards), a number of businesses indicated that, on occasions, Member States had refused to accept the validity of a CE marking, largely on the grounds that the test had made use of the results of manufacturers' tests. Notified Bodies are divided on the issue, and a number of Member States have expressed concern about the safety implications (though there have been no accidents involving products whose conformity assessment test included the results of manufacturers' tests). Essentially, the key problem is the lack of clarification on the issue.</p>	<p>Authorities, DG Enterprise and Industry should clarify whether manufacturers' tests should be included within the conformity assessment, since the lack of clarification affects the operation of the CE marking system.</p>
<p>The introduction of the ICTE form made it considerably easier for businesses to transport products within the EU. However, though the blank document can be accessed online, it must still be completed in paper format and submitted to each national authority along the route of transport, a process that costs money and imposes delays.</p>	<p>DG Enterprise and Industry should publish an interactive electronic version of the ICTE form in order to make the process of transferring explosives across borders quicker and less expensive for firms.</p>
<p>A number of firms questioned whether completing an ICTE form for each country along the route of transfer adds value in security terms, and thus whether it would save money (the cost per form is estimated by firms to be between €30 and €50) if the ICTE document was only completed for the Member State where the transfer of explosives originates and terminates. This would be controversial within many Member States, however.</p>	<p>DG Enterprise and Industry should consult with stakeholders as to whether the ICTE system is necessary and whether, in its present form, it enhances security.</p>
<p>In terms of security in the industry, the Directive aimed to harmonise supervision arrangements during the transfer of explosives, and also ensure that Member States retain and make available information on firms authorised to operate in the industry. Instead, security is largely regulated at a national level, and consequently standards vary considerably between countries. This is very much an EU-wide issue, however, and there is support for collective action to enhance security.</p>	<p>DG Enterprise and Industry should consider whether the Explosives Directive should include a minimum set of security standards. There are issues, however, regarding the legal basis for action in this area under Article 95 of the Treaty, but debate on the issue would be beneficial.</p>
<p>Businesses reported that Spain and, in particular, Italy, impose additional administrative requirements on firms wishing to export explosives products onto their national markets. The Italian authorities require that businesses provide full conformity assessment reports, in</p>	<p>DG Enterprise and Industry should consider whether administrative requirements in place in some Member States constitute a barrier to trade, and thus whether the Directive should specify the</p>

Conclusion	Recommendation
Italian, for each product, for security reasons. A number of firms and Member States have reported that this adds costs and causes delays. Though not prohibited under the Explosives Directive, this goes against the principle of the Single Market.	paperwork that should accompany an explosive product when it crosses an internal border (particularly regarding language).

1 INTRODUCTION

1.1 This report

This Final Report (Explosives Directive) is the fourth deliverable of the study 'Evaluation of DG Enterprise and Industry Legislation: Cosmetics and Explosives Directives', commissioned by DG Enterprise and Industry from EEC (GHK and Technopolis). It follows on from the Revised Inception Report that was submitted on 2 March 2007, the Progress Report that was submitted on 16 April 2007, and the First Findings and Recommendations Report that was submitted on 25 June 2007.

1.2 The purpose, aims and objectives of the study

As set out in the study specification published by DG Enterprise and Industry on 12 September 2006, the purpose of the evaluation is to compile, assess and present information on the Explosives Directive in terms of its impact and application, in order to define the potential for improvement.

In order to achieve this goal, the study specification defined the aim of the evaluation as:

'to assess the utility and effectiveness of the Directive, its impact on companies in the EU, trade barriers that limit the free movement of goods, and the application of the Directive in the Member States'

Alongside these aims, the study specification identified four objectives for the evaluation:

- § To identify, test and apply methodologies for evaluating the effectiveness, impact and utility of the Explosives Directive;
- § To define the barriers to the optimal application of the Directive;
- § To define any actions that may need to be taken in order to eliminate these barriers;
- § If deemed necessary, to provide recommendations to contribute to the re-examination of the Directive.

The methodology employed by the study to address these objectives is reviewed in Section 2.

1.3 The explosives industry

For the purposes of this study, explosives for use by the armed forces and the police have been excluded, and so the area of interest is the civil explosives industry. This includes the following end-users:

- § The mining industry;
- § The quarrying industry;
- § Construction and civil engineering, mainly for demolition, land clearance and tunnelling;

- § Other industrial uses, such as metal fabrication and activities where rapid force is required (such as air bags).

In terms of scale, the mining and quarrying industries consume the majority of explosives. In the US – the only country for which data across all uses are available – coal mining accounted for 68% of total demand, quarrying and non-metal mining a further 13%, metal mining 8%, construction 8%, and other industrial uses the remaining 3%. Proportions are likely to be different for the EU where coal mining takes place on a much smaller scale, but unfortunately there are no data available.

Explosives tend to be sub-divided into low and high, the distinction based on the rate of detonation and the amount of pressure exerted. Low explosives include black powders and propellants, and are often used in dusty or gaseous environments (such as coal mines) where accidental detonation is a major risk. High explosives are often split into two categories:

- § Primary explosives are extremely sensitive to impact, friction and heat, and are usually used in order to initiate an explosion in another, safer charge of explosives (via a commercial blasting cap, for instance).
- § Secondary or base explosives are too insensitive to be detonated by low levels of impact, friction and heat, and are instead usually initiated by a detonating wave from another source (such as from a blasting cap). Secondary high explosives are widely used in commercial or civil applications, and include dynamites, TNT and RDX.

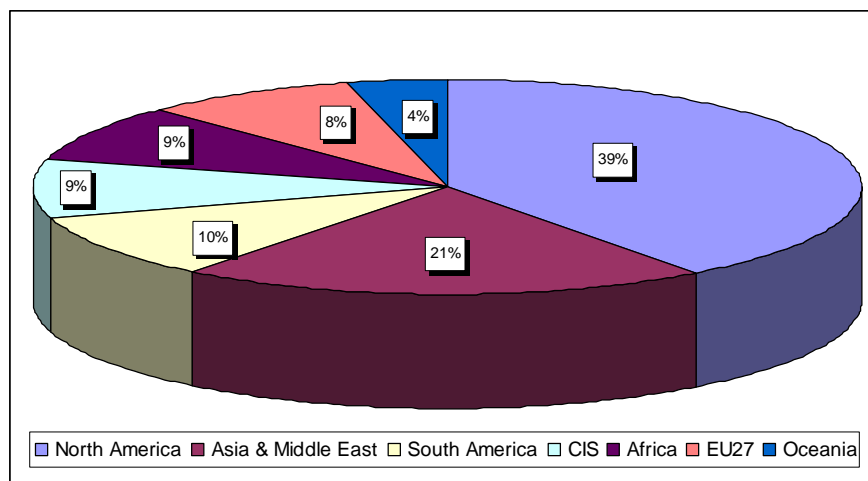
A further group of explosives are known as blasting agents and are characterised by the fact that they are so insensitive to shock that they require an intermediate primer or booster of secondary explosives for detonation (these are sometimes included as high explosives). The most common example is an ammonium nitrate and fuel oil mixture known as ANFO, and also emulsion, water gel or slurry explosives (which are suited to underwater usage). Blasting agents account for the bulk of the commercial explosives market since they are more economical and less dangerous to use and manufacture than high explosives. It has been estimated that, in 2003, 52% of Western European explosives consumption by weight consisted of ANFO, 33% of emulsions, and 15% of dynamites¹.

The explosives themselves are the main product produced by the industry. In addition to the various types of explosives discussed above, there are differences in the mode of 'delivery', including: on-site mixing of ANFO (banned on security grounds in many countries, including Spain), factory manufactured, sensitivised and packaged products (such as dynamites and emulsion- or water gel-based ANFO in cartridges or bags), and bulk explosives (such as 'dry' ANFO and emulsions or water-based slurries). Reflecting usage levels, the bulk method of delivery is growing in popularity, yet raises challenges in terms of the safe transportation of large quantities of non-sensitivised explosives, and thus requirements for multiple distribution centres. In addition to the explosives, producers also manufacture initiation systems (detonators and boosters), and other accessories.

¹ CEH Marketing (2004) Marketing Research report: Explosives and Blasting Agents. It is not clear whether this only relates to explosives consumption in the mining and quarrying industry.

The market for civil explosives in Europe is relatively small by international standards (Figure 1.1). In 2001 North America consumed around 2.5 million tonnes of explosives (39% of the global total), and Asia a further 1.3 million tonnes (21% of the global total). The EU27 countries accounted for just 8% of global consumption (0.5 million tonnes). The report from which these figures are drawn concluded that explosives consumption in Europe is 'stagnant'². However, the data only include consumption in the mining and quarrying industries. Consultees in a number of the Member States have indicated that in the EU these two sectors typically constitute a much lower proportion of overall consumption than elsewhere, meaning that 8% may well be an underestimate of the European share of consumption. Without data this cannot be verified either way.

Figure 1.1: The EU27 share of global consumption of explosives (tonnes) by the mining and quarrying industry

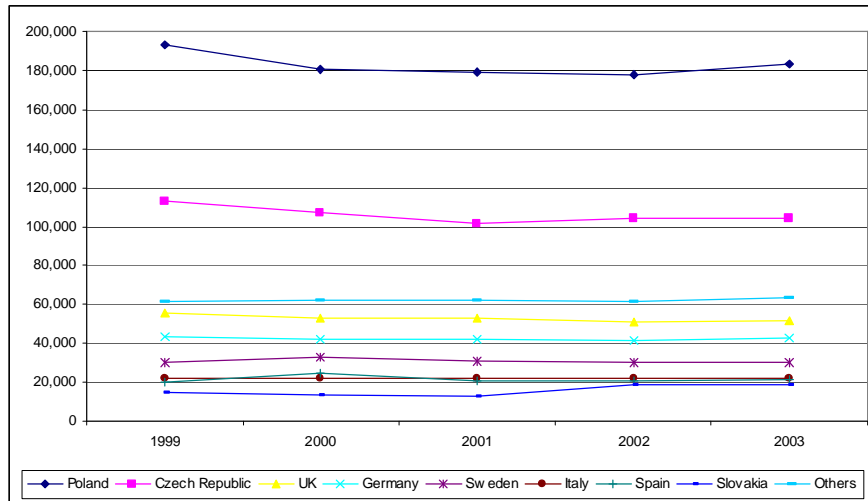


Source: CEH Marketing

Of the 27 Member States, two of the accession countries – Poland and the Czech Republic – are the largest consumers of explosives (Figure 1.2). Within the EU15, the UK, Germany and Sweden are the next biggest markets. As Figure 1.2 shows, however, levels of consumption throughout the EU27 have been largely stagnant in the past few years (though again this is just the mining and quarry industries, and excludes civil engineering and manufacturing, both important sources of demand in the EU). Total EU27 consumption of explosives stood at 554,000 tonnes in 1999, before falling to 524,000 tonnes in 2001. Consumption in 2003 amounted to 534,000 tonnes.

² CEH Marketing (2004) *op cit*

Figure 1.2: Member State consumption of explosives (tonnes) by the mining and quarrying industry, 1999-2003



Source: CEH Marketing

1.4 The Explosives Directive

The Explosives Directive (Council Directive 93/15/EEC) was adopted by the European Council in April 1993 to regulate the civil explosives market in Europe (excluding pyrotechnical devices and explosives for use by the police or armed forces)³. Member States had until June 1994 to fully transpose the provisions set out in the Directive, though up until 31 December 2002 they were also allowed to permit explosives to be placed on their domestic market where they complied with previous national legislation. Of the EU-25, only Luxembourg failed to transpose the Explosives Directive and, as a result, the Commission instigated legal proceedings that were resolved through the Court of Justice in 2006 with the full transposition of the Directive.

The preamble to the Directive makes it clear that the primary purpose of the Explosives Directive was the creation of a Single Market in explosives. The main way in which this was to be achieved was through the harmonisation of product safety standards that, at the time, varied substantially between Member States. These safety standards were set at a high level of protection, and through these the Directive has also contributed towards improving safety in the industry. However, it was recognised in the preamble that both safety and security remain largely national concerns, and consequently the Directive does not provide a comprehensive set of regulations governing either, and instead operates in conjunction with both supra-national and national legislation⁴. Security in particular is only partially addressed by the Directive (through measures designed to improve supervision and monitoring arrangements).

³ The Directive defines civil explosives as "...the material and articles considered to be such in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of these recommendations".

⁴ For instance, the Directive includes measures to enhance and harmonise safety standards governing finished explosives products. However, it does not legislate for safety in the manufacture, storage, transport or usage of these products, which are instead governed by a mixture of supra-national and national regulation (see Section 1.5).

As an example of the 'New Approach', the Explosives Directive is characterised by a combination of high safety standards coupled with flexibility⁵. The key elements of the Directive are as follows:

- § The Directive includes a set of essential safety requirements that must be met by explosives products if they are to be placed on the EU market. For each of their products, manufacturers or importers must commission an external body (see below) to carry out these safety tests that, as with other New Approach Directives, have been organised into six conformity assessment modules. The first (Module B) is compulsory, and covers minimum product safety standards (including requirements in respect of stability, resistance to temperature, sensitivity, the process of decay over time, and measures to prevent accidental detonation). Applicants must also complete another module, choosing from:
 - Module C (conformity to type)
 - Module D (production quality assurance)
 - Module E (product quality assurance)
 - Module F (product verification)
 - Module G (unit verification)
- § Importantly, the Directive does not detail the technical requirements (criteria for approval etc.) within each of these modules, which were instead drawn up and maintained by the European Committee for Standardization (CEN). In this way the conformity assessments are designed to keep pace with technological change, since altering the text of a Directive and transposing it into 27 Member State laws would be a lengthy process.
- § The conformity assessment modules are carried out by Notified Bodies – independent third party organisations that are assessed and approved by the authorities in their Member State. At present there are 14 Notified Bodies in the EU that are authorised to carry out the tests for explosives products (see Section 3.3.1 for a list). The Notified Bodies tend to be government laboratories, sometimes based within academic institutions.
- § A product that has passed the requisite conformity assessment modules is entitled to make use of the CE marking. For explosives products the CE marking is *mandatory* for sale on the European market. A product with the CE marking cannot be prevented from being sold on the European market.
- § The Directive also harmonises the documentation required during the cross-border transportation of explosives products. The Intra-Community Transfer of Explosives (ICTE) document was introduced in 2004 in order to provide a consolidated template that was easily accessible for businesses⁶. The ICTE form has to be submitted by the company wishing to transport the explosives in question to each national authority along the route of transport for prior approval,

⁵ With Old Approach Directives, the text of the legislation includes detailed technical requirements, meaning that any amendments – no matter how small – must then be transposed into national law in all Member States. In contrast, under the New Approach, the text of the Directive defines the essential requirements of the legislation in much looser terms, and technical details are instead drawn up and maintained separately by recognised European Standardisation Organisations, in line with specific mandates from the European Commission. As a result, any technical changes do not need to be transposed into Member State law, and are thus much quicker to implement.

⁶ Commission Decision 2004/388/EC

and must contain a detailed description of the product, details of the manufacturer and the agent responsible for transportation, and information about the itinerary. Firms are required to keep records of cross-border transportations for at least three years.

- § The Directive is implemented and enforced at a national level by designated Competent Authorities in each of the Member States, who must ensure that all products on the market bear the CE marking.
- § Article 8 is a safeguard clause that permits Member States to order the withdrawal of an explosives product from the market if there are grounds to consider it unsafe (either through non-compliance or an incorrect application of standards). In this case the Member State taking the initiative is obliged to inform the European Commission immediately.
- § Article 14 requires Member States to maintain records of all businesses within their territories that they have licensed to work with explosives, and to make these records available to other Member States upon request.

1.5 Other relevant legislation

The explosives industry is also regulated by a number of other pieces of legislation that operate at a supra-national and national scale.

1.5.1 *Supra-national legislation*

The most important legislation operating at a supra-national level concerns the transportation of explosives products. The key modes of transportation are each covered by a different international agreement, the purposes of which are to establish minimum safety and security standards⁷. The transportation of explosives by road, for instance, is governed by the *European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)*, which was harmonised in the EU by Directive 94/55/EC. In relation to explosives, the ADR stipulates:

- § Training requirements for drivers of vehicles containing explosives;
- § Security measures (including training and the development of security plans);
- § The maximum quantity of explosives that can be transported at any one time;
- § Packaging requirements (to ensure that products are able to withstand shocks sustained during transit);
- § Package and vehicle labelling requirements, and general documentation requirements;
- § Loading and unloading requirements;
- § Construction requirements for vehicles used to transport explosives.

⁷ Road transportation is covered by the *European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)* which was drawn up by the United Nations Economic Commission for Europe; rail transportation by the *International Carriage of Dangerous Goods by Rail Agreement (RID)* drawn up by the Intergovernmental Organisation for International Carriage by Rail; sea transportation by the *International Maritime Dangerous Goods Code* prepared by the International Maritime Organisation; air transportation by the *Technical Instructions* issued by the International Civil Aviation Organisation; and inland waterway transportation by the *European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)*.

Requirements for the other three modes of transportation include similar provisions. There is some overlap between the Explosives Directive and the four international agreements, mainly in respect of the supervision of transfers. As noted above in Section 1.4, the Explosives Directive includes the ICTE document that must accompany explosives products during transit, in order to maintain a higher level of monitoring and control over the movements of explosives within the EU.

The other significant piece of supra-national legislation affecting the explosives industry is the Seveso II Directive⁸. Amongst other things, Seveso II regulates health and safety in establishments in the EU where dangerous substances (including explosives) are present above a certain threshold⁹. Health and safety in explosives manufacturing and storage establishments is generally a national concern (see below), but alongside this Seveso II includes a raft of safety management and incident control measures designed to reduce the risk and impact of a major industrial accident.

1.5.2 **National legislation**

Legislation at the Member State level still has a significant impact on the explosives industry, primarily in relation to safety and security in the industry. National authorities are also responsible for the classification of explosives that can have an impact on the movement of explosives products across borders. Classification is the process through which national authorities allocate a UN division number to explosives on their national markets, and is based on information provided by manufacturers or importers. Though this system is based on the UN Orange Book, there is scope for interpretation, such that explosives might not receive the same classification in two different countries.

Safety

The conformity assessments modules required by the Explosives Directive ensure that the finished explosives products are safe, but do not address safety during the manufacture¹⁰, storage, or usage of these products. Instead, these issues are largely dealt with by national health and safety regulations (except where premises fall under the Seveso II Directive – see above), the details of which vary between Member States. Box 1.1 summarises Member State law in respect of safety in the explosives industry in the six case study countries:

- § Safety in the explosives industry is tightly regulated at a national level. In all Member States, authorisation is required for any firm – domestic or foreign – wishing the manufacture, store, transport or use explosives (details may vary according to the type and quantity of the explosive in question).
- § These authorisations are usually dependent upon a number of safety-related requirements, the details of which are often very similar across Member States (including the minimum distance between the site of manufacture or storage and residential property, and measures designed to prevent accidental detonation – by lightning strike, for example).

⁸ Council Directive 96/82/EC

⁹ Over 10 tonnes for most types of explosive, except for those products with a low risk of explosion (UN Division 1.4) where the threshold is 50 tonnes.

¹⁰ Though the Module D test does regulate production processes, which would to some extent affect the safety of the manufacturing process. However, the bulk of this activity is covered by national health and safety legislation.

Box 1.1: National law regarding safety in the explosives industry

In **France** a licence is required in order for a business to manufacture or store explosives. The licence is granted by the local authority (prefect), based on the submission of a dossier detailing measures that will be taken to prevent accidents from occurring, and on consultation with the local police force and the regional directorate for industry. The acquisition of explosives – to store, transport or use – is also dependent upon authorisation from the prefect, and the certificate is only valid for one year.

Anybody wishing to manufacture, store, transport or use explosives in **Italy** must obtain a licence from the authorities. These licences are dependent upon the applicant meeting certain safety standards, including requirements for the minimum distance between the site in question and any inhabited buildings or pieces of infrastructure (roads, pipelines, electricity pylons etc). The transportation of explosives must also meet safety criteria regarding the nature of the vehicle, and the vehicle must also be accompanied by an escort.

In the **Netherlands**, a licence granted by the Ministry of the Environment is required for firms wishing to manufacture, store or use explosives. The licence is dependent on the business fulfilling a number of health and safety related criteria, including the level of noise and air pollution, and the minimum distance between the site in question and residential properties or other work premises.

In **Spain** a licence is required in order to manufacture, store, transport, sell and use explosives. Licences are administered by the Ministry of Industry, Tourism and Trade (the Competent Authority for explosives). Safety is a major consideration within the granting of a licence to a business, and all applicants are expected to meet national standards governing the likes of safety risks, air pollution and the safety of detonators.

In the **UK**, a licence is required in order to manufacture or store explosives. Depending on the quantity of the explosives, this licence is granted either by local government, or by the national Health and Safety Executive. The Explosives Act of 1875 (recently updated) includes a number of safety requirements in relation to the manufacture and storage of explosives, covering issues such as the minimum distance between the site in question and inhabited buildings, and the safe disposal of explosives. Businesses manufacturing or storing explosives are required to take measures to prevent explosions, and to provide protection in the event of an explosion.

Security

The main way in which the Explosives Directive affects security in the explosives industry is through the system of enhanced and harmonised requirements governing the documentation that should accompany products during transportation across EU borders. Article 14 of the Directive also requires Member States to maintain records of all businesses that they have authorised (through licensing arrangements) to operate in the explosives industry, and to make these records available to other Member States upon request. Both of these requirements concern supervision and monitoring; other aspects of security in the industry are determined at a national level, and thus the details vary significantly between Member States. In 2005 the European trade federation for civil explosives (FEEM) carried out a survey of the minimum security

standards in place in 11 EU countries¹¹. Though now somewhat out of date (see the Netherlands case study in Box 1.2), the results of this exercise highlight the inconsistency of Member State regulations regarding security arrangements during the manufacture, storage and transit of explosives:

- § During the *manufacture* and *storage* of explosives, almost all respondents to the survey indicated that their national legislation requires a secure perimeter and secure buildings (covering construction, locks and restricted access). Less common (mentioned by around half of Member States) were regulatory measures such as the vetting of employees by the authorities, detailed records of production and storage, and alarms on buildings).
- § During the *transit* of explosives there are a number of measures that almost all Member States require, including: locks on vehicles, notification of authorities and training for staff. Around half of the Member States surveyed indicated that they also require more detailed authority approval of transit arrangements (including the route and the type of explosives being transported). The strictest regulatory measures (including an armed escort to accompany the vehicle, tracking systems and remote stopping facilities) were much less common, present in less than a quarter of the 11 Member States surveyed.
- § Finally, Member States also reported that mandatory security requirements might be in place during the *usage* of explosives. In general these were less common (present in around half of Member States), and included the likes of restricted access to the site, verification of use of explosives, and vetting by the authorities of employees. Around a quarter of respondents reported that their national legislation insisted on measures such as an armed security presence or external verification of the use and disposal of explosives.

Box 1.2 summarises Member State law in respect of security in the explosives industry in the six case study countries:

- § National security requirements regarding explosives in the six case study countries are probably the strictest in Europe (with the exception of the Netherlands). Many laws were developed in response to a specific terrorist or criminal threat (ETA in Spain and France, the IRA in the UK, and the Mafia in Italy).
- § Common security requirements reported by consultees include secure perimeters and premises, alarm systems and 24-hour surveillance. Most authorities also insist that a licence is needed from the police for the storage or acquisition of explosives, the granting of which may be dependent on a background check of the applicant, an inspection of the facility in question, and even the completion of a security audit by an accredited third party.
- § Evidence from survey responses reveals that there is a mixture of approaches towards industry security in the other Member States. In many cases these would appear to be relatively stringent (such as a requirement that armed personnel accompany the transportation of explosives in Bulgaria), but in other cases it is clear that regulations are much less strict (such as in the Netherlands, though this is currently being changed).

¹¹ Unpublished data provided by DG Enterprise and Industry

- § Variations in security requirements have implications for the operation of the Single Market. In some countries these regulations impose considerable costs and delays that, although not applied in a discriminatory way, go against the principle of removing trade barriers. This is discussed further in Section 3.4.1.

Box 1.2: National law regarding security in the explosives industry

Security related legislation in **France** has become considerably stricter in the past few years, in response to the threat posed by international terrorism. In 1999 members of ETA stole dynamite from a warehouse in Plévin, Brittany, prompting a tightening of regulation governing the storage of explosives. In December 2005 three separate laws were passed that further strengthened security requirements for premises where explosives are manufactured or stored. Measures include a secure perimeter, interior alarm and detection systems, and 24-hour surveillance. Moreover, businesses are also required to undergo a security assessment by an accredited external body (usually an independent risk assessment and safety testing company), the results of which must be authorised by regional government. Where changes are required, these must be monitored by the same external body. This assessment is only valid for five years, after which it must be carried out again.

In **Germany** a licence is required for any firm wishing to manufacture, store, transport or use civil explosives. The licence is dependent upon a number of safety and security related considerations, including the ability of the applicant to prove that they have the necessary specialist technical knowledge and expertise to work with explosives, and consideration of their 'reliability'. Background checks are carried out on applicants (including whether they have a criminal record and whether they have been a member of extremist political parties), and a register of licensees is held by the intelligence services. A licence is required for any firm wishing to transport explosives in Germany and is again dependent upon a set of safety and security conditions, including a background check on the applicant. Firms from other EU countries wishing to transport explosives in Germany do not have to have obtained this licence (though an ICTE form is required), but there must be somebody present during transit who has a licence.

Security in the explosives industry in **Italy** is regulated by the Framework Law on Public Order and Security. Requirements are relatively strict, and have largely been developed in response to the threat posed by the Mafia (there were a number of incidents in the 1990s where explosives were stolen and used for criminal activity). As noted above in Box 1.1, a licence from the Ministry of the Interior and/or the police is required for anyone wishing to manufacture, store, import, transport or use explosives, and this is only granted provided certain security standards are met (such as 24-hour surveillance of the establishment for which the application is made). The police usually carry out an inspection of the facility in question, and also a background check on the applicant before a licence is granted. The police also require notification if explosives are to be transported, and this can only be carried out where there is a 'genuine need'.

In the **Netherlands** there are currently no specific security requirements, and arrangements are instead left to the discretion of the individual establishments. In 2007 a number of inspections of premises where explosives are manufactured or stored will be carried out by the Ministry of the Environment, part of which might involve advice and recommendations regarding security measures. During the

granting of a licence to manufacture, store or use explosives, the police will also carry out a background check on the applicant. In the next year or so, security arrangements in the Netherlands will become much stricter as new laws come into force that stipulate minimum security standards, detail recommended training for employees of the explosives industry, and also establish protocol in the event of employee kidnapping, armed raids etc.

National legislation governing security and explosives is very strict in **Spain**, and in fact is widely considered to be the strictest in the EU. Regulations have been developed in response to the terrorist threat posed by ETA, and more recently by Islamic terrorists following the Madrid train bombings of March 2004. Specifically, a licence to manufacture, store, use or transport explosives is dependent upon there being adequate security measures in place. These measures include armed guards present at all premises and during the transportation of explosives. For commercial storage facilities companies may choose to install video surveillance and an alarm system in place of an armed guard, but only if prior permission is obtained from the Civil Guard. Furthermore, in all activities involving explosives (manufacturing, storage, transport, and usage), firms must fill out a formal Security Plan that must be approved by the Civil Guard. The authorities have also published specific security requirements covering the exact physical and electronic security requirements for storage facilities (for instance the number of guards per square metre, the extra surveillance requirements for larger facilities), and also the types of electronic surveillance equipment that are allowed as a substitute or supplement for armed guards.

Security arrangements for explosives in the **UK** are amongst the strictest in the EU – a legacy of the historical problems with domestic terrorism. In the 1990s there was a national upgrading of security arrangements at sites where explosives were manufactured or stored that tightened requirements considerably. Anybody wishing to acquire or keep explosives must obtain an Explosives Certificate from the local police force, who will undertake a background check on the applicant to determine their suitability. Premises where explosives are manufactured or stored must also meet a number of security related criteria, though these do vary in detail between police forces. At a minimum, however, facilities must be kept locked, and should also include an alarm system that is capable of alerting the organisation responsible for security at the site (such as a private security firm). The Health and Safety Executive has also issued guidance on recommended security arrangements for the storage of Ammonium Nitrate.

1.6 Intervention logic for the Explosives Directive

Intervention logics set out the 'logic model' that underpins a piece of legislation such as the Explosives Directive, reviewing the nature of the problem, the ways in which the Directive works, and its expected outcomes and impacts. Table 1.1 presents an intervention logic for the Explosives Directive, the components of which are analysed in greater detail in Section 3.

Table 1.1: Intervention logic for the Explosives Directive

Aspects of the intervention logic	Elaboration
<i>The problem that the Directive was designed to address</i>	

Aspects of the intervention logic	Elaboration
Clarity	The problem was clear – a need to develop a Single Market in explosives, and a need to increase safety and enhance security. No information is available on the research carried out in support of the legislation.
Nature	<p>The Directive was primarily introduced in order to remove perceived barriers to trade with the EU. It is understood that, at the time (1993), national regulations governing explosives (primarily regarding product safety testing and certification requirements) were inconsistent, and consequently there was not a level playing field within which businesses could compete.</p> <p>Regarding safety in the industry, there was a need to raise product safety standards by harmonising the safety tests at a high level. From this it is implicit that it was felt that safety tests in some countries were not as rigorous as in others, though there is no evidence available to verify this either way.</p> <p>Security in the industry is only indirectly affected by the Directive (through a harmonisation of the paperwork required for the cross-border transportation of explosives, and by requiring Member States to maintain records of all businesses authorised to operate in the explosives industry and to make these records available to other Member States upon request). Again there is no evidence about the scale of the security problem in 1993.</p>
Magnitude	No assessments of the magnitude of the problem were made prior to the adoption of the Directive.
Trends	<p>There is no systematic collection of trend data (since 1993) at an EU level on the problems that the Explosives Directive was designed to address.</p> <p>Data on the volume and value of intra-Community exports of explosives are available between 1999 and 2006, and point towards a steady increase in trade over this time period. Information provided by businesses suggests that the EU has become a slightly more important market since 1993, though most also reported a growth in global sales.</p> <p>Trend data on safety in the explosives industry are also inconsistent. At an EU level major accident data indicates isolated incidents since 1993, though none of these were caused by factors that the Directive controls. Instead, accidents tend to result from human error or equipment malfunction during the manufacturing process (for instance in 2003, an explosion at a dynamite cartridge workshop – believed to have been caused by faulty equipment – killed four people).</p> <p>Trend data on security breaches are also difficult to obtain since Member States are reluctant to publish such information (though consultees indicated that such events are very rare). Moreover, the Directive only covered security in terms of supervision and paperwork requirements, and so security breaches at facilities where products are manufactured, stored or used could not be attributed to a failing of the Directive.</p>
<i>Treaty and the legal base to act in the area</i>	
Treaty	<p>Article 95 (ex Article 100a) of the Treaty requires the Council to adopt measures for the approximation of the laws in Member States which have as their objective the establishment and functioning of the internal market.</p> <p>Article 95 also stipulates that the Commission and the Council, concerning proposals relating to health, safety, environmental protection and consumer protection, take as a base a high level of protection.</p>
Restrictions and limitations to EU level action	<p>Member States have exclusive competence to determine whether, when and which measures are necessary and proportionate in order to facilitate the free movement of goods in their territory.</p> <p>Member States are permitted to temporarily derogate from the requirements</p>

Aspects of the intervention logic	Elaboration
	of the Directive in the event of a serious threat to, or attack on, public safety.
<i>The objectives of the Directive</i>	
General objectives	<p>To ensure the free movements of (explosives) goods through the harmonisation of national safety standards.</p> <p>The Directive also aimed to improve product safety standards by harmonising the testing process at a high level. Objectives regarding security only relate to enhanced supervision in the industry (the collection of data on cross-border movements of explosives, and on national authorisations and licences).</p>
Targets, benchmarks or milestones	The objectives were not expressed quantitatively.
<i>Key aspects of the intervention process of the Directive</i>	
The main components of the Directive	<p>The Directive:</p> <ul style="list-style-type: none"> § Establishes a harmonised set of safety tests that explosives products intended for the EU market must undergo. § Creates a standard marking that products passing these tests may use (the CE marking), without which products must not be placed on the EU market. Products with the CE marking must not be prevented from entering the EU market. § Creates a standardised document for use during the cross-border transportation of explosives.
The main delivery mechanisms and responsibilities for the implementation of the Directive	<p>EU level:</p> <ul style="list-style-type: none"> § The Commission must instigate legal proceedings against Member States or businesses found to be infringing the Directive. § CEN develops and maintains the technical standards that are applied to products during the conformity assessments carried out by Notified Bodies. <p>National level:</p> <ul style="list-style-type: none"> § Competent Authorities identify and assess the Notified Bodies that will carry out the conformity assessments, ensuring that they possess the technical skills to do so. § Notified Bodies carry out the conformity assessments on explosives in such a way as to meet the essential safety requirements in the Directive, according to the specifications drawn up by CEN. § Competent Authorities carry out in-market surveillance to ensure that all products on their national market bear the CE marking and remove from the marketplace those that do not.
The effects anticipated	<p>The removal of potential barriers to cross-border trade (varying safety and labelling requirements between Member States).</p> <p>A more rigorous testing of the safety of explosives and an improved system for ensuring that products on the European marketplace meet these safety requirements.</p> <p>Harmonised and enhanced supervision of the industry leading to improved security.</p>
Mechanisms for	No systematic mechanism was put in place at the EU level. As a result of

Aspects of the intervention logic	Elaboration
measuring effects	the Seveso II Directive data are collected on serious industrial accidents, but these do not apply to all premises in the EU where explosives are manufactured, stored or used, and does not include explosives in transit. Member State monitoring of effects is inconsistent and there are issues around whether information on the thefts of explosives is publicly available.
Impacts anticipated	Increased trade in explosives products between Member States. Fewer accidents caused by faulty explosives products, and fewer security breaches during cross-border movements of explosives.
Learning processes	Notified Bodies meet on an annual basis to review industry trends and the conformity assessment process. The Article 13 Committee (made up the Member States and the Commission) meets to review the Directive.
Complementarity with other EU instruments	The Directive was designed to complement international agreements on the transportation of hazardous materials (ADR etc.)
<i>Pre-conditions for the Directive to be successful, risks and assumptions</i>	
Preconditions for success	There needed to be consensus between Member States on the necessity to undertake measures to improve the flow of trade and to protect public safety and security.
Critical assumptions underpinning the Directive, and risks	The effectiveness and impact of the Directive is reliant upon: <ul style="list-style-type: none"> § Competent Authorities identifying suitably qualified and independent Notified Bodies to carry out the safety tests, and thereafter checking to ensure that the Bodies remain suitably qualified. § Competent Authorities ensuring that explosives on the national market carry the necessary CE marking, and removing from the marketplace those that do not comply. § The safety tests evolving to keep pace with innovation in the industry. § Member States ensuring that explosives being transported have the necessary documentation. § The Commission being informed by Member States or by businesses where the Directive is being breached by other Member States (for instance if CE marked products are banned), and acting on this information to resolve the problem.
<i>The rationales underpinning the intervention at the EU level</i>	
EU added value	The added value arose as the EU was the most appropriate level at which to implement the cross-border harmonisation of product safety standards.
A need for common action	Common action was required in order to ensure a uniform set of product safety standards across the European Union.
A need to improve policies and practices	There is no direct evidence, but it is implicit that the quality of product safety testing across the Member States was variable.
A need to harmonise policies and practices	Harmonisation of product safety testing etc. was required in order to create a level playing field and reduce the costs for businesses associated with product testing and administration.

1.7 The Structure of the Report

The remainder of the report is structured as follows:

- § Section 2 outlines the methodology employed;
- § Section 3 presents the results of the evaluation, considered in terms of the problems that the Directive was designed to address, the application and implementation of the Directive, its effectiveness and impact, and finally its utility;
- § Section 4 sets out the draft conclusions and recommendations of the evaluation.

Annex 1 lists the individuals consulted during the course of the evaluation, and Annex 2 lists the individuals who responded to the Member State and business surveys. Annexes 3 and 4 provide copies of the Member State and business surveys, whilst Annex 5 contains the case studies of the Explosives Directive in six Member States. Annex 6 provides a review of the counterfactual – whether the same effects could have been achieved through means other than EU legislation.

2 RESEARCH METHODOLOGY

2.1 Evaluation tasks and questions

The study specification issued by DG Enterprise and Industry outlined a set of tasks that the evaluation was required to carry out:

- § To validate and refine the proposed methodological approach to the evaluation work;
- § To collect, analyse and present the necessary data to answer a set of evaluation questions. Data analysis should include the selection of a set of appropriate indicators to assess the effectiveness of the Directive;
- § On the basis of the evaluation findings, to provide robust and useable conclusions and recommendations to improve the Directive and its application in the Member States;
- § To present findings and recommendations in a final evaluation report;
- § To assess the counterfactual – the extent to which the same effects could have been achieved through means other than EU legislation.

The evaluation questions as set out in the study specification are as follows:

- § How is the Explosives Directive implemented in the Member States?
- § What are the barriers to the effective application of the Explosives Directive, if any? How could such barriers be overcome?
- § What have been the strengths and weaknesses of the Explosives Directive? Which parts have been more or less effective?
- § To what extent has the Explosives Directive contributed to the development of an efficiently operating internal market for explosives goods?
- § What have been the impacts of the Explosives Directive on European companies? Has it added costs or administrative burdens?
- § To what extent could measures be taken to improve the utility of the Explosives Directive, and what measures would these be?

2.2 The study methodology

The methodology for the evaluation was outlined in the revised study proposal submitted to DG Enterprise and Industry on 19 October 2006, and finalised following a kick-off meeting held between the steering group and core members of the study team on 12 December 2006. The study was divided into seven tasks:

- § Task 0: Inception phase;
- § Task 1: Assessment of the nature and scale of the problems that the Explosives Directive was designed to address;
- § Task 2: Elaboration of the nature of the explosives industry;
- § Task 3: Definition of the intervention logic for the Explosives Directive;
- § Task 4: Assessment of the application and implementation process;

- § Task 5: Evaluation of the effectiveness and impact of the Explosives Directive;
- § Task 6: Conclusions and recommendations.

These tasks can also be grouped into three phases, based on the research activities undertaken:

- § Tasks 0 to 3: a detailed review of the operation of the Directive in principle, and the nature of the problems that it was designed to address. This work drew largely on desk-based research, together with discussions with the individuals at DG Enterprise and Industry responsible for overseeing the Explosives Directive.
- § Tasks 4 and 5: analysis of the actual implementation of the Directive within the Member States, its effectiveness, and also its impact. This work was based on a number of pieces of fieldwork, including a survey of all 27 Member States, detailed case studies of 6 Member States, and a survey of the leading businesses in the explosives industry.
- § Task 6: the evaluation conclusions and recommendations, based on the results of the two previous phases of research.

Table 2.1 below summarises the way in which these three phases of the study contributed to answering the research questions outlined above.

Table 2.1: The research questions and the study tasks

Research question	Tasks 0-3 (desk-based)	Tasks 4 and 5 (fieldwork)	Task 6 (conclusions)
How is the Directive implemented in the Member States?		•	
Are there any barriers to implementation?		•	
What are the strengths and weaknesses of the Directive?	•	•	•
Has the Directive contributed towards the Single Market in explosives?	•	•	
What have been the impacts of the Directive on EU firms?		•	
What measures could be taken to improve the utility of the Directive?		•	•

The remainder of this section consists of a review of the activities undertaken within each of these three phases of the research.

2.3 Tasks 0 to 3: Desk-based review of the evidence

Task 0: Inception phase

Work commenced with a kick-off meeting held between the steering group and core members of the study team on 12 December 2006. At this meeting, key sources of information and initial contacts within DG Enterprise and Industry were identified. Following this meeting, the team conducted a detailed review of the text of the Explosives Directive and carried out two telephone interviews with the key individuals

from DG Enterprise and Industry (see Annex 1). Upon completion of this work, an Inception Report was submitted to the steering group, and approved following a meeting held on 2 February 2007.

Tasks 1 and 2: Review of the nature of the problem that the Directive was designed to address, and the nature of the explosives industry

These two tasks were completed in unison, and involved a wider desk-based review of the available evidence on the nature of the explosives industry and the associated regulatory issues. It had been assumed that information would be readily available on topics including: the way in which the Member States were implementing the Directive, trends in safety in the explosives industry (such as data on the number of accidents), and also trends in security in the industry (including data on the rates of thefts and incidents of criminal or terrorist misuse of explosives). During this phase of the study, however, it transpired that such information is either not publicly available, or is not published for the EU as a whole.

Limited data regarding the economic structure of the explosives industry were collected, including trend data for 1999-2006 from Eurostat on intra-Community exports and the production of explosives, and also data on the country-by-country consumption of explosives¹². From this it was possible to make limited observations about the nature of the explosives industry in the EU, but further information from businesses was required in order to draw more substantial conclusions about the problems that the Directive was designed to address.

Task 3: Definition of the intervention logic for the Explosives Directive

This final piece of desk-based research involved a synthesis of the previous work in order to define and intervention logic for the Explosives Directive. This activity set out the 'logic model' that underpins the Explosives Directive, reviewing the nature of the problem, the ways in which the Directive works, and its expected outcomes and impacts. A draft of the intervention logic was included in the Inception Report.

Following the completion of Tasks 1 to 3, results were written up to form a Progress Report that was submitted to the steering group and approved following a meeting held on 17 April 2007.

2.4 Tasks 4 and 5: Fieldwork with Member States and businesses

The purpose of these two tasks was to determine the views of Member States and businesses on the implementation, effectiveness and impact of the Explosives Directive. It was initially envisaged that this could be accomplished through six case studies, and a small business survey. However, the lack of published information on the application and implementation of the Explosives Directive meant that it was impossible to establish how the legislation was actually working across the EU without surveying all of the Member States. This work was not included in the study proposal, but it became clear that it was essential in order to supplement the detailed case studies and provide a more comprehensive picture of the operation of the Directive.

¹² The latter from CEH Marketing (2004) *op cit*

Task 4: The application and implementation of the Explosives Directive

The bulk of this work consisted of an investigation into the ways in which the Explosives Directive is applied within the Member States. As noted previously, it was decided that the most appropriate way in which to complete this work was a survey of all 27 Member States. The survey was prepared by the study team and reviewed by the steering group at the inception meeting. A copy of the survey instrument is attached as Annex 3. DG Enterprise and Industry provided contact details for each of the Competent Authorities¹³ and the Notified Bodies. On 15 March 2007 the survey was sent via email to 25 Competent Authorities and 13 Notified Bodies¹⁴. A postal version of the survey was sent to the Romanian Competent Authority since no email address was available. On 12 April 2007, the Competent Authorities and Notified Bodies who had not replied were sent a reminder email, and during the week beginning 14 May 2007, the Member States who had still not responded were contacted by telephone.

A total of 18 Competent Authorities returned the survey, equating to a response rate of 69% (Table 2.2). Two Notified Bodies returned the survey individually, whilst another five replied as part of the submission by their national Competent Authority (equating to a response rate of 54%). Annex 2 lists the individuals from the Competent Authorities and Notified Bodies who responded to the survey.

Table 2.2: Responses to the survey of Member States

Member State	Organisation	Response to survey?	Member State	Organisation	Response to survey?
Austria	Competent Authority	No	Latvia	Competent Authority	No
Belgium	Competent Authority	Yes	Luxembourg	Competent Authority	Yes
	Notified Body	No	Malta	Competent Authority	Yes
Bulgaria	Competent Authority	Yes	Netherlands	Competent Authority	Yes
	Notified Body	Yes		Notified Body	No
Cyprus	Competent Authority	Yes	Poland	Competent Authority	Yes
Czech Republic	Competent Authority	Yes		Notified Body	Yes
		Notified Body	Yes	Portugal	Competent Authority
Denmark	Competent Authority	Yes	Romania	Competent Authority	Yes
Estonia	Competent Authority	Yes		Notified Body	Yes
Finland	Competent Authority	Yes	Slovakia	Competent Authority	No
	Notified Body	No		Notified Body	No
France	Competent Authority	Yes	Slovenia	Competent Authority	Yes
	Notified Body	Case study	Spain	Competent Authority	Yes

¹³ Excluding Lithuania where no contact details were available.

¹⁴ The 14th Notified Body – TÜV Rheinland InterCert in Hungary – was not listed on the NANDO database at the time of the survey, and so was not included in the survey.

Member State	Organisation	Response to survey?	Member State	Organisation	Response to survey?	
Germany	Competent Authority	Case study		Notified Body	Yes	
	Notified Body	Case study	Sweden	Competent Authority	No	
Greece	Competent Authority	Partial			Notified Body	Yes
Hungary	Competent Authority	No	UK	Competent Authority	Yes	
Ireland	Competent Authority	No			Notified Body	Yes
Italy	Competent Authority	Yes				

Though the survey provided a comprehensive picture of how the Directive is applied throughout the EU, the case studies of six Member States were an opportunity to explore in more detail why authorities chose to implement the Directive as they did. Case studies were completed in six Member States (France, Germany, Italy, the Netherlands, Spain, and the UK), and are attached as Annex 5. The choice of Member States was made by DG Enterprise and Industry in consultation with the study team, and included a mixture of approaches to the implementation of the Directive. For each case study, face-to-face interviews were completed with individuals from the Competent Authority and, where possible, the Notified Body. Failing this, a representative from the Notified Body was subsequently interviewed over the telephone. A list of the individuals consulted during the case studies is included in Annex 1.

Finally, in order to determine the views of businesses on the Explosives Directive – and in particular whether there are any remaining barriers to trade – a survey of the leading firms was carried out (see Annex 4 for a copy of the survey). The survey was prepared by the study team and validated by the steering group at the progress meeting. Contact details were provided by FEEM (the trade federation for the civil explosives industry), supplemented by an internet search for businesses in the sector. The survey was emailed to 26 firms on the 16 May 2007, and followed by telephone in June and July 2007. A total of 10 replies were received, equating to a response rate of 38%. Annex 1 lists the individuals from businesses who responded to the survey. Key characteristics of the businesses that responded to the survey are as follows:

- § A mixture of small, medium and large firms responded to the survey. The smallest firm employed 30 people, whilst the largest consisted of a group of companies and employed over 1,000 people.
- § All but one of the respondents manufactured prepared explosives, including most or all of: dynamites, ANFO (packaged and bulk), emulsion explosives (cartridged and bulk), and watergels and slurries.
- § All but one of the respondents also manufactured detonators and related articles.
- § Other activities that respondents engaged in included the manufacture of fireworks and the provision of explosives-related services (primarily logistics).

FEEM was also asked to comment on the Explosives Directive and the Single Market, but no response was received.

Task 5: The effectiveness and impact of the Explosives Directive

Effectiveness and impact were considered in terms of the goals of the Explosives Directive, primarily in respect of the Single Market, and also safety and security in the industry (considered under Task 2). Effectiveness can be assessed through consideration of the ways in which Member States have gone about applying and enforcing the Directive, and how businesses view their activities (Task 4). Impact can be considered through – for instance – trend data on trade and industrial accidents (though as noted above, there is almost no published information in these areas, and certainly nothing going as far back as 1993 when the Directive was adopted). Alongside this, as part of the survey Competent Authorities and Notified Bodies were asked to comment directly on the effectiveness and impact of the Explosives Directive. Again, through the case studies these issues were explored in much greater depth, exploring whether consultees in Member States felt that certain parts of the Directive were ineffective, and why this was the case.

Businesses were asked to provide evidence about the impact of the Directive on their operations, considered in terms of data on exports of explosives, and also the costs and delays associated with the demands of the legislation. Furthermore, firms were asked to comment on whether the implementation of the Directive varies between Member States, and if so whether this has a specific impact on their company.

2.5 Task 6: Conclusions and recommendations

The final task for the study was to draw together the evaluation results and present a set of conclusions and recommendations. Upon completion of this task, a First Findings and Recommendations Report was produced for discussion at a steering group meeting held on 4 July 2007. Comments received from the steering group were incorporated into this Final Report.

3 EVALUATION RESULTS

3.1 Introduction

This section of the report presents the results of the evaluation of the Explosives Directive, and is organised as follows:

- § A review of the nature of the problems that the Explosives Directive has been designed to address, looking at the operation of the Single Market, safety in the industry, and security in respect of the transportation of explosives.
- § Details of the application and implementation of the Explosives Directive in the Member States, exploring the system of product conformity assessment and the operation of the Notified Bodies, in-market surveillance by the Competent Authorities, and the usage of the ICTE document.
- § Analysis of the effectiveness and impact of the Explosives Directive with regard to its aims to develop a Single Market in explosives, to improve safety in the industry, and to enhance security.
- § A review of the utility of the Explosives Directive, which will inform the evaluation conclusions and recommendations (Section 4).

3.2 The problems that the Explosives Directive was designed to address

Prior to the adoption of the Explosives Directive in 1993, there appears to have been no published assessment of the nature and scale of the problem(s) that the legislation was designed to address. It is implicit that the measures to facilitate the Single Market were intended to remove barriers to trade, increase the intra-Community flow of explosives products, reduce costs, and improve the competitiveness of EU firms. Furthermore the Directive was also introduced in order to improve safety in the industry and reduce the number of accidents, whilst to a lesser extent the legislation also affected security. Unfortunately there is no comprehensive picture of the magnitude of these problems in 1993; indeed, trend data since then are inconsistent and make it hard to assess how these problems have changed over time.

3.2.1 *The Single Market*

The primary reason for the introduction of the Explosives Directive was to facilitate the development of a Single Market in explosives. The implicit reasoning behind this move is that, back in 1993, it was felt that there were a number of barriers to trade in operation that needed to be removed. As noted previously, no published information is available to verify this. Data on the volume and value of intra-Community trade in explosives are only available as far back as 1999, six years after the introduction of the Directive. However, this data does suggest that levels of trade have increased in the past few years (Figures 3.1 and 3.2):

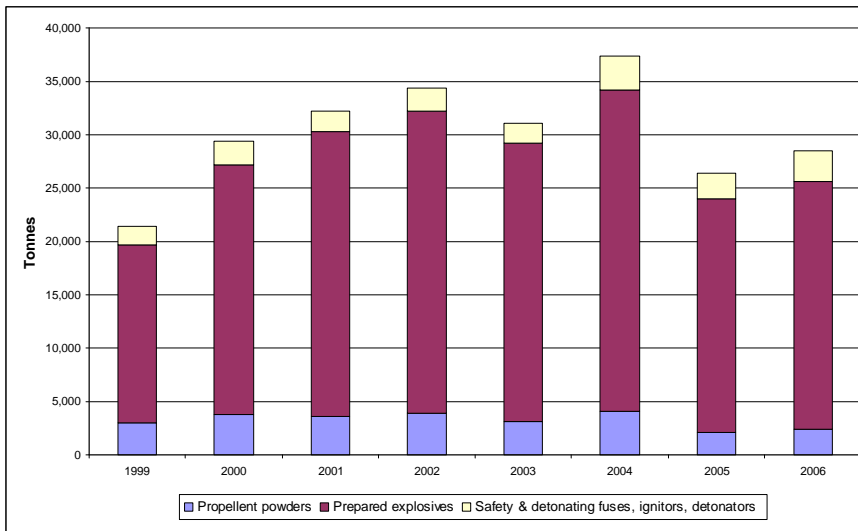
- § In 2006, intra-Community trade in explosives goods¹⁵ within the EU27 amounted to 28,000 tonnes, with a value of €135.1 million. Prepared explosives represented the bulk of trade when considered in terms of volume (23,300

¹⁵ Explosives has been defined as HS (2002) 3601, 3602 and 3603

tonnes in 2006), but most of the value was generated by trade in fuses, igniters and detonators.

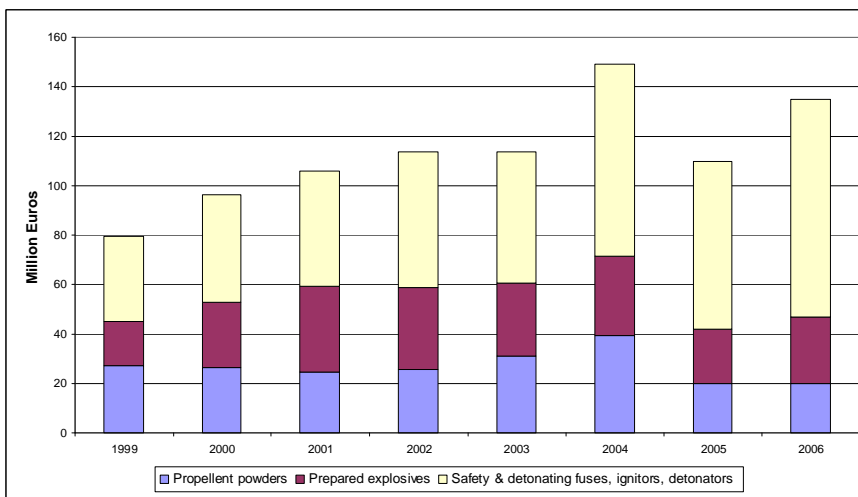
§ The volume and value of intra-Community trade in explosives has fluctuated since 1999. Levels of trade grew steadily through till around 2002, before dipping in 2003, and then peaking in 2004. The volume of intra-Community trade in 2006 was marginally less than in 2000, though value picked up and is currently second only to 2004.

Figure 3.1: Volume of intra-Community trade in explosives (EU27)



Source: Eurostat

Figure 3.2: Value of intra-Community trade in explosives (EU27)



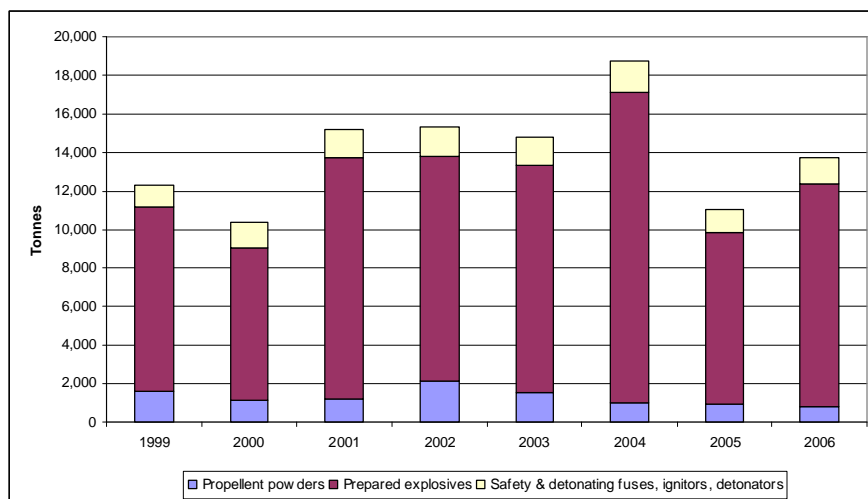
Source: Eurostat

Eurostat data also provide information on the global trade in explosives. One of the reasons for the establishment of the Single Market was to increase the competitiveness of European firms, which would be reflected in the export performance of the Member States. Figure 3.3 shows the volume of exports of explosives products

from the EU27 to the rest of the world between 1999 and 2006, and Figure 3.4 shows the value of these exports:

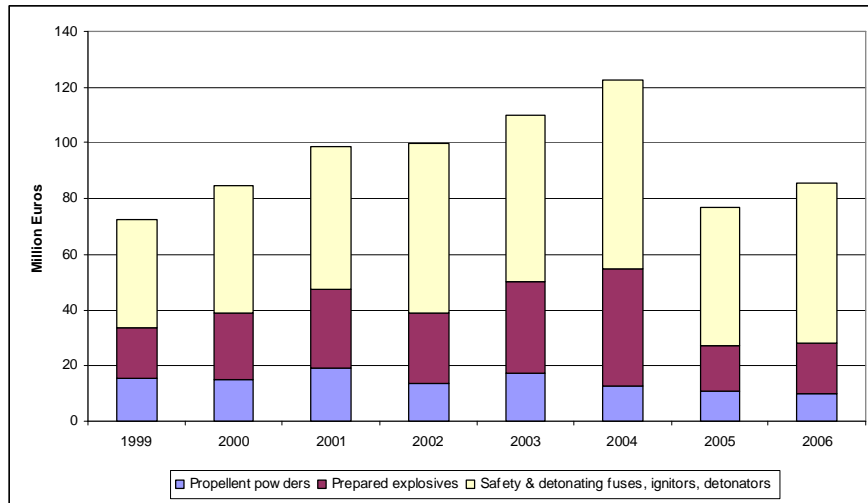
- § Between 1999 and 2006 the volume of exports from the EU27 to the rest of the world fluctuated with no discernable trends. The volume of trade peaked in 2004 when exports amounted to just under 19,000 tonnes (of which 16,000 tonnes were prepared explosives). In 2006 exports of explosives products from the EU27 to the rest of the world amounted to 14,000 tonnes, compared to 28,000 tonnes of intra-Community trade.
- § The value of EU27 exports to the rest of the world increased steadily between 1999 and 2004 (peaking at €122.6 million), before dropping to €85.6 million in 2006. As above, the bulk of this value was generated by exports of fuses, igniters and detonators (worth €57.9 million in 2006). By way of a comparison, the value of intra-community trade in explosives in 2006 was €135.1 million.
- § In terms of individual countries, other European states were the largest market for exports from the EU27, in particular Croatia, Norway, Bosnia and Herzegovina, and Switzerland. In 2006, for instance, Croatia accounted for 21% of the total volume of exports from the EU27 and Norway a further 16%. The United States is also a significant market for goods; in 2006 exports from the EU27 amounted to 1,700 tonnes, or 13% of the total export volume.
- § The volume of exports of explosives from the EU27 to the other major markets of the world is relatively low. After the United States, China is thought to be the largest global market, yet the total volume of exports from the EU27 amounted to just 4 tonnes in 2006. In the same year, exports to South Africa, Russia and India were 4 tonnes, 55 tonnes and 56 tonnes respectively, tiny fractions of overall consumption in these countries.

Figure 3.3: Volume of exports of explosives products from the EU27 to the rest of the world (1999-2006)



Source: Eurostat

Figure 3.4: Value of exports of explosives products from the EU27 to the rest of the world (1999-2006)

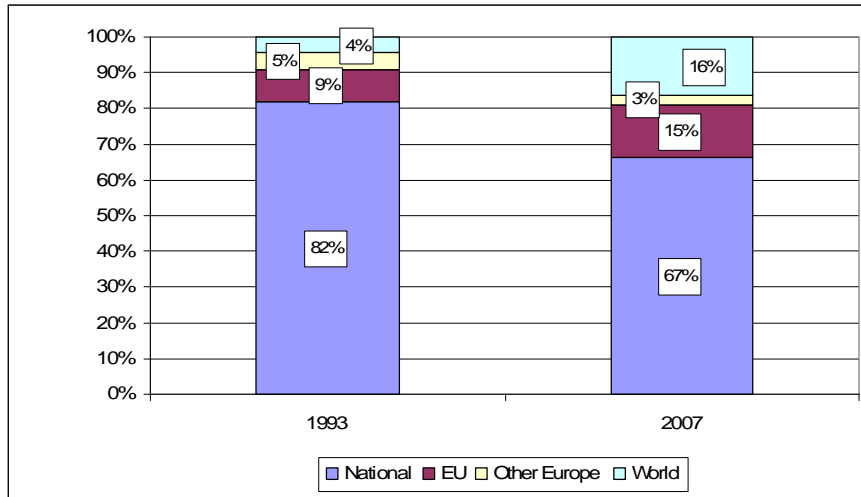


Source: Eurostat

The survey of businesses carried out as part of this evaluation also looked at broad trends in the industry that help identify how the nature of the problem that the Directive was designed to address has changed since 1993. Firstly, as part of the survey, businesses were asked to indicate the average proportion of their sales derived from a selection of markets in 1993 and the present (Figure 3.5). As can be seen, respondents are now much less dependent on their national market. In 1993, businesses reported that, on average, 82% of their sales came from the domestic market; the current proportion is 67%. Firms now generate 15% of their sales from elsewhere in the EU, up from just 9% in 1993. Alongside this the world market is of increasing importance (currently accounting for an average of 16% of sales amongst respondents), suggesting that firms are increasingly taking advantage of global markets (though as noted above, trade data suggest that the United States accounts for most of the exports to non-European countries).

Overall, however, firms still derive the majority of their income from meeting national demand, and though steady progress has been made towards an EU or even global orientation, the data suggest that the Single Market in explosives is still at an early stage.

Figure 3.5: The proportion of sales that businesses derived from intra-Community trade, 1993 and 2007



Base = 8 businesses

Businesses were also asked to assess whether the volume of their exports to the rest of the EU had changed since 1993. The picture was mixed: of the ten respondents, five reported that levels had remained the same, four reported an increase, and one a decrease. Asked to comment on these trends, respondents noted that:

- § The industry in Europe is going through a period of consolidation and restructuring with firms forming a small number of groups of companies with subsidiaries in a number of EU countries.
- § The accession of 12 new Member States triggered a programme of expansion amongst established Western European firms to take advantage of the new opportunities.
- § At the same time, Western European firms have faced growing competition from companies based in the accession states, many of which benefit from lower labour costs.
- § There are also changes underway in the nature of the market with a decline in the use of dynamites and a growth in the use of emulsions (partly in response to the nature of demand from the Eastern European Member States).

3.2.2 Safety and security

Safety

Assessing the scale of the problem in terms of the safety of explosives is problematic since there is no consistent, EU-wide database on the number of industrial accidents involving explosives. As part of the implementation of the Seveso II Directive (that regulates safety in facilities where large quantities of explosives are manufactured or stored – see Section 1.5.1), the Major Accident Reporting System (MARS) was established in order to maintain a database of all industrial accidents in Seveso II regulated establishments. MARS provides data as far back as 1982. Though it is not comprehensive (premises where explosives are present below the set threshold for

Seveso II will be excluded), this gives an indication of the scale of the safety problem in the EU, and how it has changed over time.

Analysis of the MARS database has shown that there have been a number of serious accidents involving explosions since 1982, but that the majority of these have not involved explosives products. Where explosives products have caused an accident, it is usually fireworks that are to blame; the 2000 explosion in a fireworks depot in Enschede in the Netherlands that killed 23 was the most serious event since 1993. Just five incidents were recorded on the MARS database involving civil explosives:

- § In 1991 an explosion occurred at a facility for the disposal of explosives, though there were no fatalities;
- § In 1993 there was an accident at a German factory where blasting explosives were manufactured that killed two people. The cause was thought to be an equipment malfunction during the production process;
- § In 2002 one person was killed by an explosion at a factory manufacturing propellant explosives, again caused by equipment malfunction during the production process;
- § In 2002 an explosion occurred at a factory where gelatinous rock explosives were manufactured, caused by equipment malfunction during the production process;
- § In 2003, an explosion at a dynamite cartridge workshop killed four people. The cause was not determined, but was likely to be either equipment malfunction or human error during the production process.

In each of the cases listed, the cause of the accident was equipment malfunction or human error during the manufacture of the product, rather than the result of a fault with the finished explosive.

In the UK, a search of the Health and Safety Executive's EIDAS database (which records all explosives accidents since 1875) showed that there had been a total of 111 incidents involving explosions since 1993. Of these, 34 involved fireworks (the single most common category), followed by accidents involving military explosives or ammunition, then explosions resulting from the use of chemicals in the manufacturing industry. Accidents involving civil explosives products are extremely rare and were always a result of human error or misuse, usually during the manufacturing process or the disposal of unwanted explosives. Neither a search of the EIDAS database nor consultation with the Health and Safety Executive resulted in the identification of a single incident where a finished explosive had malfunctioned and caused an accident.

Security

Consistent EU-wide data on the magnitude of the security problem associated with civil explosives are impossible to obtain, largely because Member States can be very reluctant to put such information into the public domain. Consequently it is hard to assess the nature or scale of the problem, and whether it has changed since 1993.

Consultations with the authorities carried out during the case studies have revealed that there have been almost no incidents where explosives have been stolen and misused for criminal or terrorist purposes in the past few years. For example, neither

the Health and Safety Executive in the UK nor the Ministry of the Environment in the Netherlands could recall a single case since 1993, though the IRA were active during this time in the UK. National security arrangements regarding manufactured civil explosives tend to be very strict, and threats are equally as likely to come from homemade or improvised explosive devices.

The notable exception was the Madrid train bombing of 2004 that was carried out using illegally obtained manufactured civil explosives. Indeed, the issue of security and explosives is probably most relevant in Spain, where security arrangements are probably the most comprehensive and strictest in the EU (including a requirement that armed guards are present at all times at premises where explosives are stored and during transit). Terrorists from ETA have, in the past, stolen explosives in France where security regulations were historically less rigorous, and then used them in Spain. In 1999, for example, members of ETA stole dynamite from a warehouse in Plévin, Brittany, prompting a tightening of regulation governing the storage of explosives in France. In general, however, events such as these are notable for their rarity, and thus it is difficult to discern any trends since the Directive was introduced in 1993.

3.3 The application and implementation of the Explosives Directive

As an example of the New Approach, the Explosives Directive is relatively flexible in terms of its implementation requirements. Competent Authorities have a number of legal responsibilities, but these tend to relate to the end result (keeping non-compliant products from the market), and how they get there is very much left to national discretion. For instance, though the Directive requires that Member States ensure that all explosives products bear a CE marking, there are no requirements in terms of the mechanisms through which this would be achieved (in-market surveillance, customs inspections etc). Consequently there is potential for significant variation in the details of the enforcement of the Explosives Directive between Member States, which could ultimately affect its effectiveness and impact.

There are a number of aspects to the Directive – the critical assumptions listed in the intervention logic presented in Section 1.6 – where the application and implementation of the legislation within the Member States is particularly important to its overall effectiveness. These are:

- § How the Notified Bodies carry out the conformity assessments, and whether these assessments are uniform across the EU.
- § How the performance of the Notified Bodies is monitored by the Competent Authorities.
- § The scale of in-market surveillance carried out by Competent Authorities to ensure that products on the national marketplace comply with the Directive.
- § How the intra-Community transfer document is working in practice.

There follows a review of the approaches that the Member States have taken with regard to each of these four aspects of the Directive, drawing on the survey and case studies of the Competent Authorities and Notified Bodies, and the survey of businesses.

3.3.1 Conformity assessments and the Notified Bodies

The Explosives Directive does not specify the technical content of the conformity assessment, instead providing general guidance on the types of test that should be undertaken. The technical standards are instead defined by CEN, and most were not published until 2002 or 2003 (before this, national standards were still in use). At present there are a total of 61 published standards covering the civil explosives industry¹⁶. The conformity assessments are carried out to the CEN specifications by certified Notified Bodies. The NANDO database (New Approach Notified and Designated Organisations Information System) currently lists 14 Notified Bodies within the EU that are authorised to carry out tests on explosives products¹⁷.

The scale of conformity assessments

A total of 13 of the 14 Notified Bodies were surveyed in order to establish the scale of the conformity assessment activity underway in the EU in the past few years¹⁸. Seven Notified Bodies responded¹⁹, and the results are summarised in Table 3.1. Each year, respondents reported that they carried out around 175 conformity assessments (all Modules). In 2005 and 2006, just under half of these were Module F tests (product verification), making it the single most popular Module. There were no Module E (product quality assurance) or Module G (unit verification) tests carried out by the Notified Bodies who responded to the survey. It is relatively rare for a product or company to fail a conformity assessment test. In 2004 for instance, respondents indicated that there had been no failures, though in 2006, 5% of conformity assessments failed.

Table 3.1: The number of conformity assessments undertaken by selected Notified Bodies (2003-06)

Year	Module B		Module C		Module D		Module F		All Modules	
	Total	Failed	Total	Failed	Total	Failed	Total	Failed	Total	Failed
2006	56	1	29	0	15	0	92	9	192	10
2005	39	0	41	0	49	0	102	5	231	5
2004	120	0	20	0	66	0	0	0	206	0
2003	50	0	17	0	7	1	0	0	74	1
All years	265	1	107	0	137	1	194	14	703	16

Base = 7 Notified Bodies

¹⁶ These are organised into product groups covering high explosives, detonators and relays, detonator cords and fuses and propellants and rocket propellants. For high explosives there are 16 separate published standards, covering issues ranging from sensitiveness to friction to resistance to water to safety in extreme temperatures.

¹⁷ They are: the Institut National De L'environnement Industriel Et Des Risques (INERIS) in France; the Laboratorio Oficial Jose Maria De Madariaga (LOM) in Spain; TNO Certification in the Netherlands; the Health and Safety Laboratory in the UK; the Bundesanstalt Für Materialforschung Und Prüfung (BAM) in Germany; SP Sveriges Tekniska Forskningsinstitut AB (SP) in Sweden; the Główny Instytut Górnictwa (GIG) in Poland; the Centre De Contrôle De Carnelle ASBL in Belgium; the Finnish Defence Forces Research Institute Of Technology in Finland; VVUU AS in the Czech Republic; and Konstrukta-Defence JSC in Slovakia; INSEMEX-SECEMTI in Romania; Minproect JSC in Bulgaria; and TÜV Rheinland InterCert in Hungary.

¹⁸ At the time of the survey TÜV Rheinland InterCert in Hungary was not listed on the NANDO database.

¹⁹ Those based in: Bulgaria, the UK, Sweden, Romania, the Czech Republic, Spain and Poland.

Businesses were also surveyed about the number of conformity assessments that they had commissioned in the past three years, and their reasons for choosing between the Modules on offer. Six firms provided a response, indicating that, on average, businesses undertake a total of 14 conformity assessments each year. Of these, an average of 9 will be the compulsory Module B test, 1 the Module C test, and the remaining 4 the Module D test. Explanations for the choice of Module included:

- § Whichever was cheapest;
- § Whether the businesses' manufacturing facility was accredited to ISO 9001 standard. If not then a Module C test was used, if so, then a Module D test was preferred.

Businesses were asked to rank by importance their reason for selecting which Notified Body to commission to carry out a conformity assessment. Overall there is no consistent picture, and different businesses prioritise different factors when choosing between the Notified Bodies. In general, however:

- § The time taken to complete the conformity assessments was the most important criteria for three businesses.
- § The proximity of the Notified Body to the site of manufacture was also seen as important (the most important factor to five businesses, and the second most important to another three firms). In one instance a respondent reported that, since they were required to complete an ICTE form even where samples of explosives were being transported to a Notified Body for testing, they favoured domestic or local Notified Bodies in order to reduce delays and paperwork.
- § The cost of the test was the most important criteria for just one business, but the second or third most important factor for the majority of the other respondents (see below for further details).
- § The 'quality' of the testing process carried out in the Notified Body was seen as the least important criteria on the whole.

These results highlight the fact that Notified Bodies are perceived to carry out the conformity assessments in different ways, beyond simple cost variations. This issue is important since it *can* cause Member States to question the validity of the tests carried out by certain Notified Bodies (see below – the uniformity of conformity assessments).

Costs associated with the conformity assessments

Businesses were asked to estimate the costs associated with the conformity assessment process:

- § The average minimum cost per product tested is €5,000, though one respondent noted that this figure can be as much as €50,000 where the test is particularly intensive or complex.
- § The average costs per year for conformity assessments vary depending on the scale of production, and can thus range from between €10,000 to €20,000 a year for relatively small company, to up to €300,000 for a much larger firm. The average annual cost of conformity assessments for the six businesses that provided details was €77,000.
- § Of the ten respondents to the business questionnaire, three felt that the costs associated with the conformity assessments were 'about right', six felt that they

were 'too high', and one did not provide a response. Larger firms who carried out more conformity assessments were more likely to consider the costs to be 'too high'.

- § In addition to the costs of the conformity assessments, one respondent also indicated that the time taken to complete the tests could range from between 1 and 6 months, which could impose a considerable delay on the marketing of a product.

The uniformity of conformity assessments

The uniformity of the conformity assessments is key to the effective operation of the Explosives Directive. If there are significant variations in the approach taken to the assessments by the Notified Bodies, this could affect the safety of the products tested. Furthermore, variations would also have a distorting influence on the operation of the Single Market. Less thorough tests would be likely to be cheaper, which might then be passed on to the cost of the product on the market, placing them at a competitive advantage relative to products that had been tested more comprehensively.

Evidence from across all of the New Approach Directives suggests that Notified Bodies often take different approaches to assessing products, which can lead to variations in the interpretation of the technical safety requirements, and procedural differences (such as the scale and rigour of audit processes)²⁰. These differences result from the flexibility inherent in the system, the fact that Notified Bodies are effectively in competition for business and must therefore seek to cut costs, and the difficulties that Competent Authorities have in 'policing' the quality of the Notified Bodies. As well as being a threat to public health if a potentially dangerous product is certified compliant, there is a danger that Member States will come to doubt the validity of CE marked products, and require additional safety tests, thus creating a barrier to trade.

Regarding the Explosives Directive, technical standards are set by CEN, though there remains a degree of scope for interpretation in some areas. As discussed above, businesses reported that considerations such as cost, the time taken to complete the tests, and the overall 'quality' of the process all shape their choice of assessor, suggesting that the Notified Bodies approach the conformity assessments in slightly different ways. Again, this could potentially compromise the safety of products, or could be seen to compromise safety, thus providing Member States with a justification to refuse to accept the validity of CE markings awarded by particular Notified Bodies.

Businesses indicated the following ways in which the approaches taken by the Notified Bodies vary:

- § A small number of Notified Bodies (most notably HSL in the UK, and to a lesser extent INERIS) are willing to make use of the results of certain tests carried out by the manufacturer during the conformity assessment process (though as noted above, HSL will only do so if the manufacturer has undergone a Module C assessment to ensure that their quality assurance systems are adequate). It was reported that other Notified Bodies (BAM, LOM in Spain, and SP in Sweden) insist on carrying out all tests themselves.

²⁰ SEC (2007) 173 'Impact assessment: proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products'.

- § Notified Bodies also do not always accept the results of Module tests carried out by other Notified Bodies, which can form part of other conformity assessments²¹. One business indicated that BAM had refused to recognise a CE mark awarded by GIG in Poland, meaning that the product had to be completely retested by BAM. In another instance INERIS did not accept the results of a test carried out by BAM on an electronic detonator.
- § There can be significant differences in the time taken by Notified Bodies to carry out the conformity assessments. In one instance it was reported that a comparable procedure took one month at HSL, but over six months at BAM.
- § Notified Bodies handle minor technical amendments in different ways. For instance, it was reported that in the event of changes to the brand name of a product, INERIS only required a few amendments to the accompanying technical documentation, whereas BAM treated this as an entirely new product that consequently needed a new conformity assessment.

The scale of these differences is hard to judge since only a small number of businesses responded to the survey. Of the ten respondents, only four had ever made use of more than one Notified Body and could compare experiences. Nevertheless the consequences of the issues raised above can be serious, with respondents reporting that product retesting and the resultant delays can impose considerable costs on their operations. Furthermore, differences in the approaches taken by the Notified Bodies may also contribute to the unwillingness of the authorities in some Member States to accept the validity of CE marked products from other countries (see below).

Member States and CE marked products

The principle behind the Explosives Directive is that once a product has received a CE mark from a certified Notified Body it should be considered safe by all Member States, and thus additional tests are unnecessary and constitute a barrier to trade. In practice, however, evidence suggests that this system is not operating quite as intended.

Member States reported that they always accept the validity of a CE marking, regardless of the location where the product was tested. Not to do so, it was noted, would constitute a breach of the Directive. The authorities in the UK and the Netherlands argued that there was no reason to question checks carried out by particular Notified Bodies, since the standards set by CEN are perfectly adequate, and they have full confidence in the quality control systems operating in each of the Member States where Notified Bodies are located.

Certain Member States, however, expressed concern about the quality of the conformity assessments being carried out by a number of Notified Bodies outside of their country, though they all insisted that these doubts had never culminated in the rejection of an explosives product. The Spanish authorities in particular indicated that the practice of using manufacturers' tests with the conformity assessment process (which is routine at the HSL in the UK and is also used on a lesser scale by INERIS,

²¹ Hypothetically, a firm could use one Notified Body to carry out a Module D assessment on its quality assurance mechanisms, after which other Notified Bodies might accept the results of its own internal product safety tests, thus reducing the amount of external testing required and consequently the overall cost (the approach adopted by the HSL). However, if a Notified Body refused to accept the validity of the initial Module D assessment, then this would not be the case, and a comprehensive retest would be needed. This does not affect the right of firms to sell CE marked products on national markets that is a matter for the Competent Authorities, but does add costs to the conformity assessment process.

but never takes place within the Spanish Notified Body), together with the sub-contracting of testing to third parties (this evaluation has not identified any instances where this has taken place), was thought to compromise the quality of the safety test. The issue has been subject to considerable debate within the forum of Notified Bodies, and to reiterate, guidance issued by CEN and the Commission does not preclude such practices. With regard to the use of the results of manufacturers' tests during conformity assessments, this only takes place where manufacturers have undergone a quality assurance audit. INERIS noted that in some instances – involving more modern products – manufacturers' testing equipment is superior to their own.

The businesses that responded to the survey, however, reported a slightly different picture. Of the ten respondents, five indicated that they had experienced instances where authorities in one country had not accepted the results of a conformity assessment carried out by a Notified Body in another country, and had requested additional paperwork, or even a retest. Italy, Spain and France were identified as countries where this had taken place. Examples provided by respondents included:

- § A case where the Italian authorities had refused to permit the importation of a product given a CE marking by BAM (it has not been possible to verify this with the Italian authorities).
- § National authorities refusing to accept CE markings on reclaimed military explosives, despite these tests being carried out by VVUU in the Czech Republic and Konstrukta-Defence JSC in Slovakia. The firm in question noted that if reclaimed military explosives are deemed unsafe, then a CE marking should never be awarded, but that the lack of clarification on these products causes problems.
- § For all products, the Italian authorities require that documentation and technical drawings (including those associated with the CE marking) are translated into Italian and that this translation is legally certified (it can be hard to find anybody with the expertise to carry out this certification, other than a Notified Body).

In balance it is difficult to ascertain how widespread the problem is, since authorities in each of the Member States mentioned by businesses deny that they have ever rejected a CE marked product. The French authorities reported that in the past there had been misunderstandings that were quickly resolved, but that these are inevitable in an industry where the safety of products is paramount, and there is a significant amount of technical paperwork involved. It would seem that such events are infrequent and based on particular products, rather than anything systematic, and are likely to have been more a feature of the early phase of implementation of the Directive (a 'bedding-in' stage).

One business indicated that they believed these incidents to be motivated by a desire by authorities to protect their national marketplaces from competition, but this opinion was not voiced by any other respondent. Perhaps more of a concern is the perception of a number of businesses that there are no appropriate mechanisms in place for the resolving such disputes. National authorities, it was felt, still have the power to cause delays at borders through obstruction and bureaucratic barriers, and that the process of complaining to companies' 'home' government would take too long to be worthwhile. No respondents indicated whether they had raised these problems with the European Commission.

3.3.2 Ongoing quality control of the Notified Bodies

Article 6 of the Explosives Directive indicates that responsibility for ensuring that the Notified Bodies are capable of carrying out the conformity assessments to the required standard lies with the Member States. Each Notified Body was initially assessed and certified by their national Competent Authority or a national accreditation body, based on their ability to carry out safety tests to a professional and impartial standard (Annex III of the Directive). Following this, Member States are required to ensure that the Notified Bodies remain able to complete the conformity assessments, though the Directive does not specify how this monitoring process should operate.

In practice it is clear that there is little in the way of systematic post-certification monitoring of the Notified Bodies. The Competent Authorities in the UK and the Netherlands both reported that they maintain close informal contacts with their respective Notified Bodies, but have not carried out any technical inspections. In part this is due to the high level of technical expertise required to assess the activities of the Notified Bodies, beyond examination of quality control procedures and the attainment of other relevant accreditations. In Germany BAM submits annual reports to the Competent Authority detailing the tests that it has carried out, and any issues that have emerged. In France quality control is more systematic and a committee within the Ministry of the Economy carries out checks at INERIS twice a year, including analysis of how the Notified Body actually conducts safety tests.

Alongside formal monitoring by the Competent Authorities there is also a system of informal quality control operating between the Notified Bodies. All Notified Bodies meet once or twice a year to discuss the conformity assessment process and trends in the explosives industry as a whole. Moreover, though they are technically in competition, Notified Bodies do provide assistance to each other. A representative from the HSL recently spent time with the Romanian Notified Body (INSEMEX-SECENTI) in order to share good practice and work towards improving quality standards. Representatives from all of the Notified Bodies consulted indicated that they believe such informal network-based mechanisms to be sufficient to ensure that any quality problems with a particular Notified Body would be identified. Competent Authorities also considered the present system to be satisfactory.

The four largest Notified Bodies (INERIS, HSL, BAM and TNO Certification) are also part of two international expert groups: IGUS (the International Group of Experts on the Explosive Risks of Unstable Substances that was created by the OECD) and the UN Expert Committee on the transport of explosives. Again, it was reported that these networks ensure a high degree of information sharing and informal quality control.

3.3.3 In-market product surveillance

Competent Authorities are responsible for ensuring that products on their national market comply with the requirements of the Explosives Directive. Primarily this role involves in-market surveillance to check that products bear a CE marking and the requisite accompanying paperwork. However, the Directive does not specify how this process should be carried out, nor does it provide detail on protocol in the event of the discovery of a non-compliant product, beyond an obligation that it is removed from the marketplace. Consequently there is evidence of a range of approaches taken by the Competent Authorities. Common activities included:

- § Monitoring of documentation received during applications for permission to transport explosives.
- § Product checks by customs officers at the point of importation into the national market.
- § Inspections of manufacturing and storage facilities, and locations where explosives are used.

The scale of this activity varies significantly between Member States, and some authorities are more thorough than others. This is a reflection of the scale of the task (in smaller countries where the use of explosives takes place on a relatively limited scale it is easier to check all products) and also the level of commitment of the Competent Authorities to inspections (reflected in the scale of resources provided etc). Box 3.1 summarises the approaches taken in each of the six case study countries.

Box 3.1: The scale of in-market surveillance in the Member States

In-market product surveillance in **France** is organised by the Ministry of the Economy. Every year the Ministry publishes an annual inspection plan that is implemented by its regional directorates. The annual total budget for inspections is around €100,000. On average 12 premises where explosives are manufactured, stored and used are inspected each year, usually at random, but on occasions in response to notification of a possible breach of the law. Activities include checks to ensure that all products bear a CE marking, and also a small number of product tests to verify conformity.

In-market surveillance in **Germany** is coordinated centrally by the Federal Ministry of the Interior. The checks are carried out by authorities in the 16 Länder who visit manufacturing and storage facilities and sites where explosives are used in order to ensure that products bear a CE mark and are labelled correctly. In the event of non-compliance the Länder are required to inform the Competent Authority, though since the Directive was introduced in 1993 it is not thought that there has been a single instance where a product was found not to have a CE marking (though there have been a small number of labelling problems – between 5 and 10 since 1993). Overall the authorities report that the explosives industry in Germany is made up of a small number of firms with many years of experience. Competition in the industry is such that any firm producing faulty products would quickly be identified.

In **Italy**, the systematic inspection of explosives products in manufacturing and storage facilities, as well as locations where explosives are used commenced in 2005. Sites where explosives are used are inspected twice a year. Inspections are usually carried out randomly, though the authorities also conduct surveillance based on requests from sub-national government.

In the **Netherlands**, the Competent Authority (the Ministry of the Environment) had not carried any systematic in-market surveillance prior to 2007, largely due to the small scale of the domestic explosives industry, and a lack of familiarity with the requirements of the Directive. In 2007, however, the Department of Inspection and Enforcement within the Ministry of the Environment launched an annual programme of surveillance, which in 2007 will involve visits to 40 premises where explosives are manufactured, stored or used in order to check that products bear a CE marking and possess the necessary paperwork.

In **Spain**, in-market product surveillance is the joint responsibility of the Competent Authority and the Notified Body. Products are checked to ensure that they comply with the requirements of the Explosives Directive throughout the supply chain, from production facilities through to sites where explosives are used. Unfortunately it has not been possible to obtain information on the scale of this activity, though the authorities reported that, in combination with the administrative requirements associated with explosives, they were confident that surveillance was thorough enough to identify any cases of non-compliance.

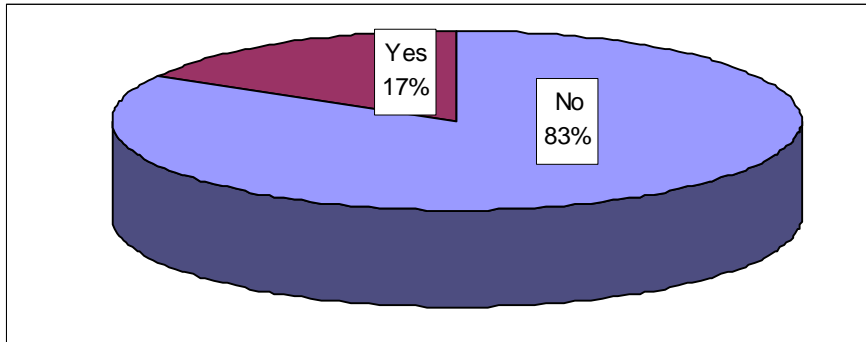
In the **UK**, inspectors from the Health and Safety Executive (the Competent Authority) carry out periodic checks on explosives products in large manufacturing and storage facilities to ensure that they bear a CE marking, and that they comply with the requirements of domestic legislation. The scale of this activity is thought to be sufficient, and in general the authorities are confident that importers and manufacturers of explosives products will comply with the Explosives Directive and domestic legislation.

Member States were asked to provide information on the number of times that non-compliant products (ie those not bearing a CE mark) had been found on the national market. Survey evidence suggests that this is a very rare event (Figure 3.6). Just three respondents indicated that they had discovered non-conforming products in the past few years: Estonia, Italy, and Portugal. In each case the explosives in question were confiscated by the authorities and destroyed, and the offender was prosecuted.

In 2006 the Italian authorities discovered an unlicensed factory where black powder was being manufactured that did not have a CE marking. Following the Explosives Directive and Italian law, the powder was seized, the factory was shut down, and the individual responsible was arrested and given a prison sentence. The Italian authorities reported that this was the only case since 1993 where a non-compliant product had been found on the national marketplace.

Given the absence of a systematic programme of in-market surveillance in many countries, it is hard to assess whether the small number of instances of products being discovered without a CE mark is a result of widespread compliance, or a reflection of the limited number of inspections. Case study Competent Authorities were asked to comment on this point, and in every instance consultees indicated that it was likely to be the former (widespread compliance), since it was in businesses' best interests to ensure that products were safe (and thus complied with the Directive). Furthermore, the relatively small size of the industry, coupled with the fact that there were usually good communication linkages between national authorities and the major explosives companies, meant that the Competent Authorities consulted were confident any persistent violations would be brought to their attention.

Figure 3.6: Have explosives without a CE marking ever been found on your national market?



Base = 18 Competent Authorities

3.3.4 The Intra-Community Transfer of Explosives Document

The ICTE document was introduced in 2004 in order to harmonise the documentation required during the movement of explosives products between Member States. Previously, Member States each produced their own versions of this document, and consequently there were variations in the details required. Firms also had difficulties in obtaining blank forms for completion, since they were only available as a paper copy from the relevant national authorities. Where a business was seeking to transport explosives across a number of borders (each requiring a separate form), the administrative costs and delays could be prohibitive, and thus acted as a barrier to trade.

In general, consultees reported that the ICTE form is working well, and has made the cross-border transportation of explosives much easier. However, there are differences in the ways in which Member States approach the ICTE form that cause uncertainties. It was reported that in a number of countries (including France and Spain), the ICTE form must be completed for each and every product movement, whereas in the UK and Germany the form is valid for a particular product for a set period of time, regardless of how many movements are made. In the Czech Republic this period of time is set at one year.

Businesses' experiences of the ICTE form were mixed. Of the ten respondents, six reported that they were satisfied with the operation of the document, three wished to see changes made, and one provided no answer. The most common complaint concerned the delay associated with having to complete the form for each and every country through which explosives were transported. Two businesses reported that this does little to increase security, but adds considerable delays and costs. One respondent noted that the process of approval could take between two and three weeks to complete, which affects their ability to respond to requests for products at short notice. A number of Competent Authorities also queried the need for approval from all authorities en route, as opposed to just those at the origin and destination.

In other cases consultees complained about the process of accessing and completing the form. The ICTE form is available from the DG Enterprise and Industry website in PDF format in the languages of the EU15. In order to simplify the process for firms, some Competent Authorities have reformatted the document and posted a

downloadable blank PDF copy on their website (the Netherlands and Germany, for instance). However, since the ICTE form only exists in PDF format, it must still be printed and completed in paper form. Firms must then fax or post the completed document to each national authority along the route of transportation for prior approval. This process was seen as highly time-consuming, and could be simplified considerably if a version of the ICTE form was made available that could be completed electronically, and then emailed to national authorities. It is understood that six Member States are currently trialling such a system under the AGIS Framework Programme project.

When asked about the administrative costs associated with the completion of the ICTE form, three respondents indicated that they were 'about right', and five felt that they were 'too high'. On average a form was thought to take between 30 minutes and 1 hour to complete. Most respondents indicated that the costs associated with the process ranged from between €30 to €50 per form. However, two firms put the cost at €250 or €300, though it is not clear whether this figure includes staff costs. One of these latter businesses estimated that each year it had to complete around 500 ICTE documents, which consequently imposed a substantial cost.

3.4 The effectiveness and impact of the Explosives Directive

Effectiveness is considered in relation to the goals of the Directive, namely to establish a Single Market in explosives, to improve safety in the industry, and to increase security.

3.4.1 The Single Market

The principal aim of the Explosives Directive was to develop a Single Market in explosives products, and thus this is the main benchmark against which to assess its effectiveness and impact. The Single Market was to be achieved through the creation of a harmonised set of safety tests carried out by certified independent Notified Bodies that would ensure that products were accepted throughout the EU. The effectiveness and impact of the Directive is dependent upon this system operating smoothly, but as discussed in Section 3.3.1 above, there is evidence that this is not always the case.

Businesses were asked whether they had experienced any barriers that had restricted their ability to export products to other EU countries since the Directive came into force (Figure 3.7). Of the ten respondents, all indicated that such barriers still existed. The joint most commonly identified – mentioned by 80% of respondents – were regulatory hurdles in other EU countries. Respondents raised the following issues:

- § The inconsistent way in which Notified Bodies and Competent Authorities approach the results of tests carried out by other Notified Bodies can result in a need for 'double approval' in some instances. One respondent highlighted authorities in Germany, Sweden, France, Poland, Spain, the Czech Republic and Italy as being particularly likely to insist on the retesting of a CE marked product. The respondent noted that the need for retesting imposed additional costs and delays, though as noted above, we have not been able to confirm this incident.
- § Respondents also indicated that mechanisms for reporting regulatory hurdles were ineffective since it was believed that the process would take a prohibitively long amount of time. It was also suggested that, in one or two cases, it was

believed that such an action would lead to 'retaliation' from the authorities in question in the form of increased bureaucratic delays.

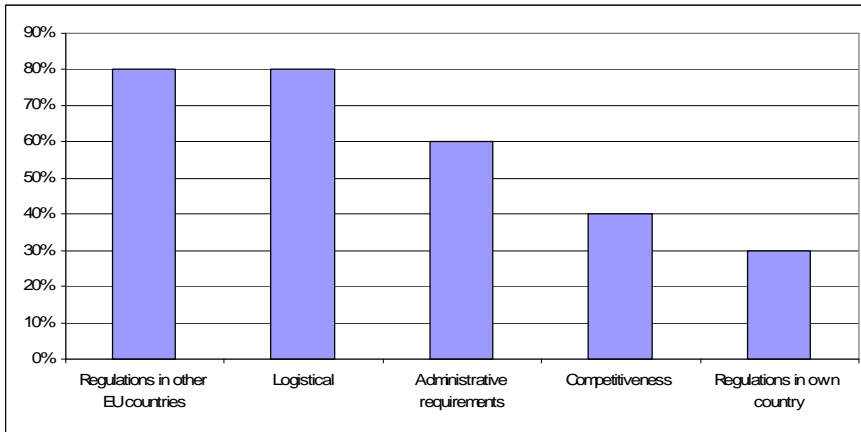
- § Requirements for the export of explosives into Spain are particularly onerous, thus increasing significantly the cost of selling to the Spanish market. Permission to export explosives to Spain must be obtained from both national government and the federal and local police forces. This process can lead to considerable delays.
- § The Italian authorities also require a considerable amount of paperwork to be completed for explosives products entering the national market, all of which must be translated into Italian. All explosives must be accompanied by detailed information describing the product, and the CE marking must have a certified legal translation. A consultee from the Ministry of the Interior reported that these requirements are needed since the authorities maintain a detailed database of all explosives present on the national market, largely for security reasons.

It is important to distinguish between the types of barrier mentioned above. The first – retesting requirements – is the most serious since it constitutes a breach of the Directive. Two different businesses reported that they had experienced this problem, yet all of the Member States consulted denied that they ever required CE marked products to be retested. As noted above, it is hard to draw any firm conclusions, though if true, this would seriously compromise the effectiveness of the Directive. On a related note, the second bullet point indicates that systems for resolving trade barriers are also considered to be ineffective by those firms that had experienced problems since they would be disproportionately resource and time intensive.

The Spanish and Italian examples given above demonstrate the effect that national safety and security regulations can have on the operation of the Single Market. The Italian authorities, for instance, require that additional information is provided about any explosives entering the national market in order to enable them to monitor all products more effectively, according to the authorities for security reasons. Security is a national issue and so the Italian authorities are not breaching the Directive, though this does go against the spirit of the Single Market by creating delays and imposing additional costs on firms.

Figure 3.7 indicates that logistical hurdles associated with transporting explosives over long distances and administrative barriers at borders were also a problem for businesses (mentioned by 80% and 60% of respondents respectively). Administrative barriers are often associated with the regulatory requirements in place in countries such as Spain and Italy, and have been reviewed above. In other cases, competitiveness reasons (primarily the low prices of explosives originating from a number of the Eastern European accession states) and domestic regulatory conditions were highlighted as trade barriers. One respondent based in Northern Ireland noted that domestic security regulations prohibit the cross-border movement of explosives into and from Ireland, thus preventing any exports to the closest export market.

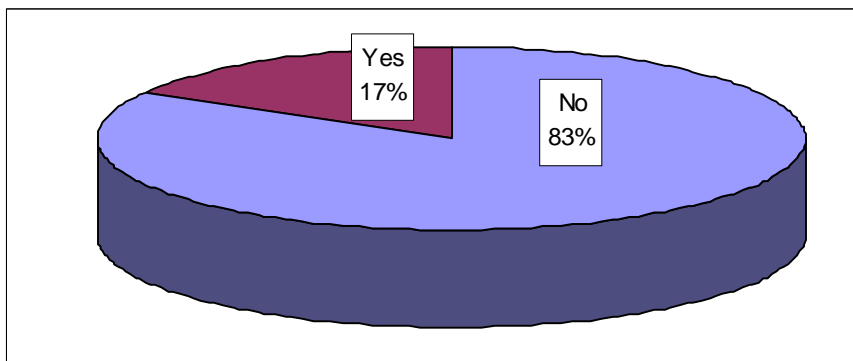
Figure 3.7: Barriers to intra-Community trade reported by businesses



Base = 10 businesses

Competent Authorities were also surveyed regarding perceived barriers to trade in the EU (Figure 3.8). In this case an overwhelming majority (83%) felt that there were no major restrictions still in place, highlighting the difference in opinion between businesses and the regulatory authorities. Two of the Competent Authorities consulted noted that they were aware that other Member States did not always accept the validity of CE markings on products, though they could not provide any examples. In another instance a respondent noted that the system through which explosives are given a UN classification could also form a barrier since this is the responsibility of Member States, yet there is no agreed system in place. The classification can be important since it determines the requirements for the transportation of products, and it is possible that authorities might challenge the validity of a classification carried out by another Member State. No examples were given, but one of the business respondents also noted that this process could potentially be used to delay the entry of products onto national markets.

Figure 3.8: Are there any remaining barriers to trade?

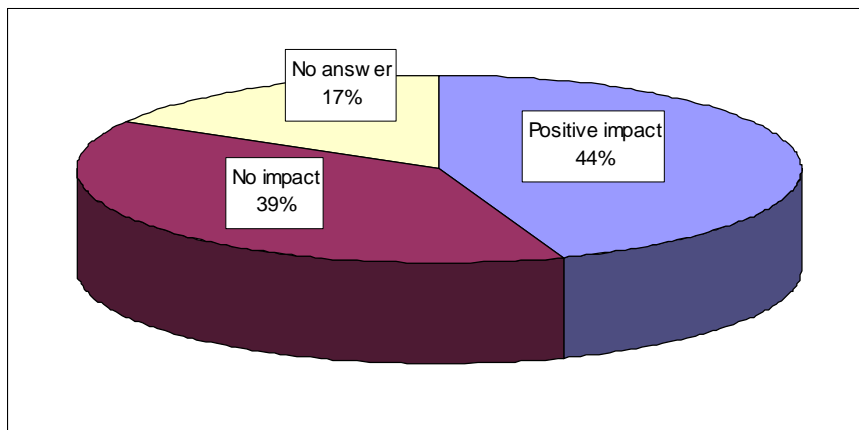


Base = 18 Competent Authorities

Competent Authorities were asked to assess the impact that the Explosives Directive has had on intra-Community trade in explosives (Figure 3.9). A Single Market should be marked by increases in the proportion of sales that firms derive from other EU

countries. As regulatory bodies whose focus was often safety and security, not all Competent Authorities felt able to judge the impact of the Directive on trade (17% of respondents gave 'no answer'). Of the remainder, 44% believed that the Directive had had a 'positive impact' on trade. Two of the recent accession states (Slovenia and Estonia) noted that the Directive had resulted in a noticeable increase in the volume of non-domestic explosives available on the national market. Some 39% of Competent Authorities felt that the Directive had had 'no impact', though a number of these were small countries where the consumption of explosives is very small (Luxembourg and Cyprus).

Figure 3.9: What impact has the Directive had on intra-Community trade?



Base = 18 Competent Authorities

The impact of the Directive on intra-Community trade in explosives – and thus the progress towards developing a Single Market – can also be gauged by analysing the export data provided by businesses. Figure 3.5 in Section 3.2.1 showed that, since 1993 when the Directive was introduced, the EU market has become more important to businesses. The average proportion of sales that respondents derived from the EU market grew from 9% in 1993 to 15% in 2007. Figures 3.1 and 3.2 presented annual data on the volume and value of intra-Community exports in explosives between 1999 and 2006, which again points towards a slight increase in EU trade. Together these various sources of information suggest that levels of trade in explosives between Member States have grown at a steady rate since the Directive was introduced, though national markets still account for the bulk of most firms' income.

3.4.2 Safety

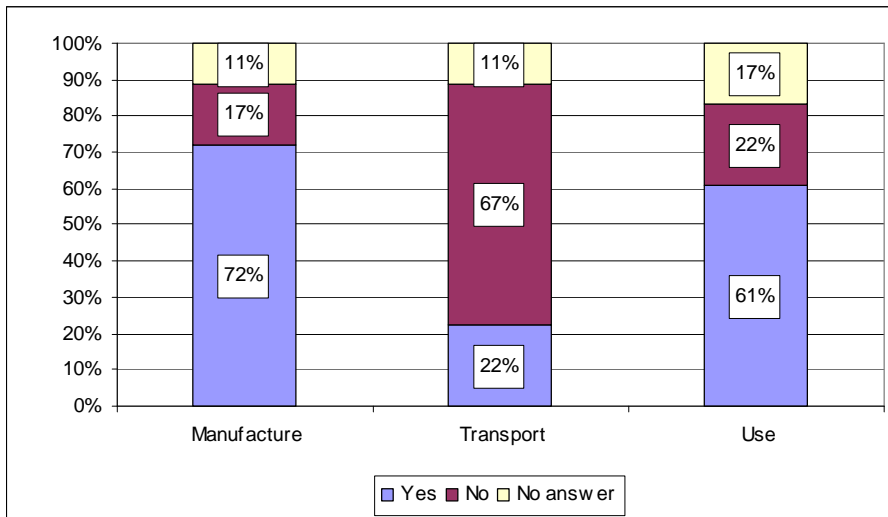
The essential safety requirements outlined in the Directive and subsequently defined by CEN were harmonised at a high level in order to improve safety standards across the European Union. The effectiveness of this activity – and thus the impact of the Directive on industrial safety – is dependent on the extent to which the safety tests are being carried out to the necessary standard, whether non-compliant products are being removed from the marketplace, and also whether the safety tests themselves remain relevant in the face of technological change.

The survey asked Member States to indicate whether they felt that the conformity assessment process ensured that the manufacture and usage of explosives is safe (see Figure 3.10). In both cases – manufacturing and usage – the majority of

respondents felt that the safety tests did improve safety (72% and 61% of respondents respectively). Where there was disagreement, in every case respondents indicated that this was because the Directive was not the only piece of legislation of relevance. Safety during the manufacturing and usage of explosives was seen to be first and foremost the responsibility of the business concerned, regulated by national health and safety legislation. The Directive was seen as effective in ensuring that the products themselves were safe, but it was felt that the greatest risk resulted from human error or the misuse of products, neither of which are affected by the Directive.

Much the same is true of safety in respect of the transportation of explosives products (Figure 3.10). Here 22% of respondents felt that the Directive ensured that the transport of explosives was safe, whilst 67% disagreed. Again, respondents noted that other legislation (primarily the ADR and RID) was more of an influence on safety in this area, and thus any improvements could not be attributed to the effectiveness of the Explosives Directive.

Figure 3.10: Is the Directive effective in ensuring that the manufacture, transport and usage of explosives are safe?



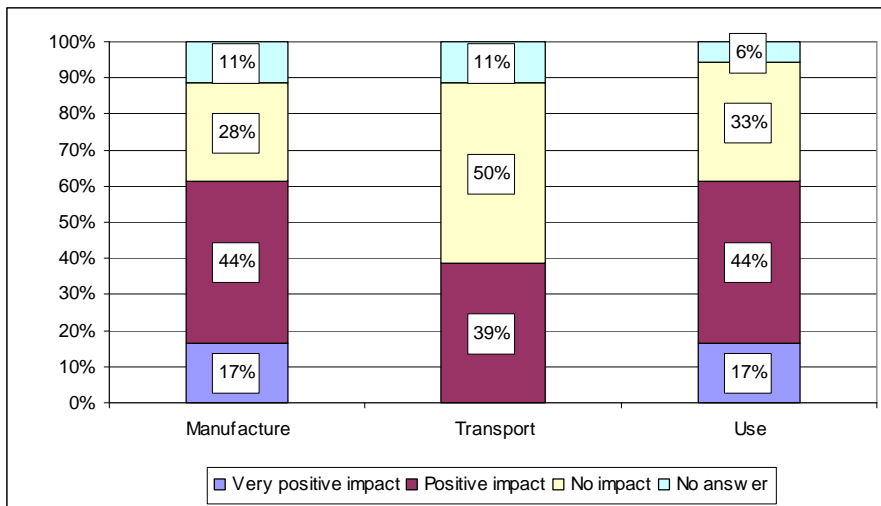
Base = 18 Competent Authorities

Competent Authorities in the Member States were also asked to comment on the impact of the Directive on safety, again during the manufacture, usage and transport of explosives (Figure 3.11). With regard to both the manufacture and usage of explosives, 17% of respondents felt that the Directive had had a 'very positive' impact, and a further 44% saw a 'positive impact'. Regarding the transportation of explosives, half of respondents (50%) believed that the Directive had had 'no impact'. As above, Competent Authorities felt that safety in the industry had been improved to some extent since finished products were seen to be inherently safer under the current testing regime. However, the biggest threat to safety in the industry was seen to come from human error or misuse, neither of which is regulated by the Explosives Directive.

Section 3.2.2 summarised the available evidence concerning major accidents in the explosives industry since 1993. Such events are very rare (five were listed on the MARS database of Seveso II regulated sites), and all of them were caused by plant equipment malfunction or human error during the manufacturing process. It is thus

difficult to draw any firm conclusions about the impact of the Explosives Directive on safety in the industry. None of the case study countries could identify a single serious accident in their domestic explosives industries, though again this was largely attributed to strict national health and safety regulations. Indeed, consultees suggested that, provided finished products were safe – and the Explosives Directive has gone as far as possible towards ensuring this – safety in the industry was not a cross-border issue, and was best dealt with by individual Member States. There are, however, Single Market implications for this approach, as discussed in Section 3.4.1.

Figure 3.11: What impact has the Directive had on the safety during the manufacture, transport and usage of explosives?



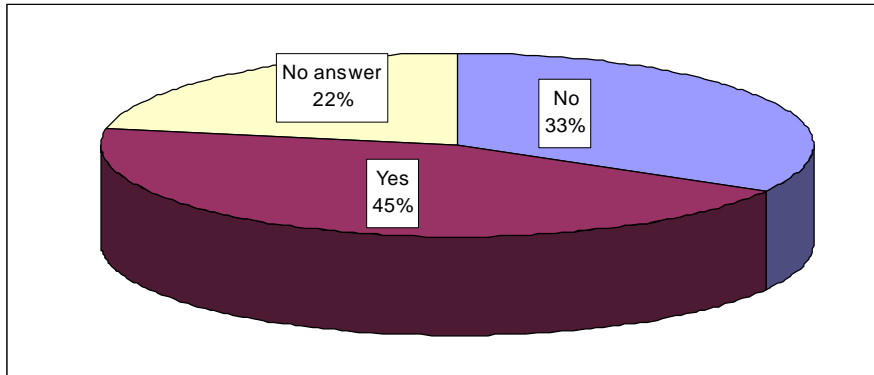
Base = 18 Competent Authorities

3.4.3 Security

Increasing security in terms of civil explosives was not an explicit aim of the Directive, though it does include measures designed to harmonise and improve supervision in the industry (by, for instance, requiring that Member States maintain records of all national authorisations and licenses that they have granted to businesses, and make these available to other Member States upon request). The ICTE document harmonised requirements for the information needed during the cross-border transportation of explosives, and made sure that this data would be made available to all Member States en route. This enhanced process of information sharing thus made it easier for Member States to track explosives entering their territory (whilst in transit and also in terms of their destination). However, beyond supervision, security in the explosives industry is not regulated by the Directive, and is instead governed by national legislation (see Section 1.5.2).

Competent Authorities were surveyed regarding their opinion on the effectiveness of the Directive in terms of raising security (see Figure 3.12). The answers reflect the points raised above, namely that the Directive has limited scope for intervention in the field of security. Some 45% of respondents felt that the Directive had been effective in enhancing security, whilst 33% disagreed.

Figure 3.12: Has the Directive been effective in enhancing security in the explosives industry?



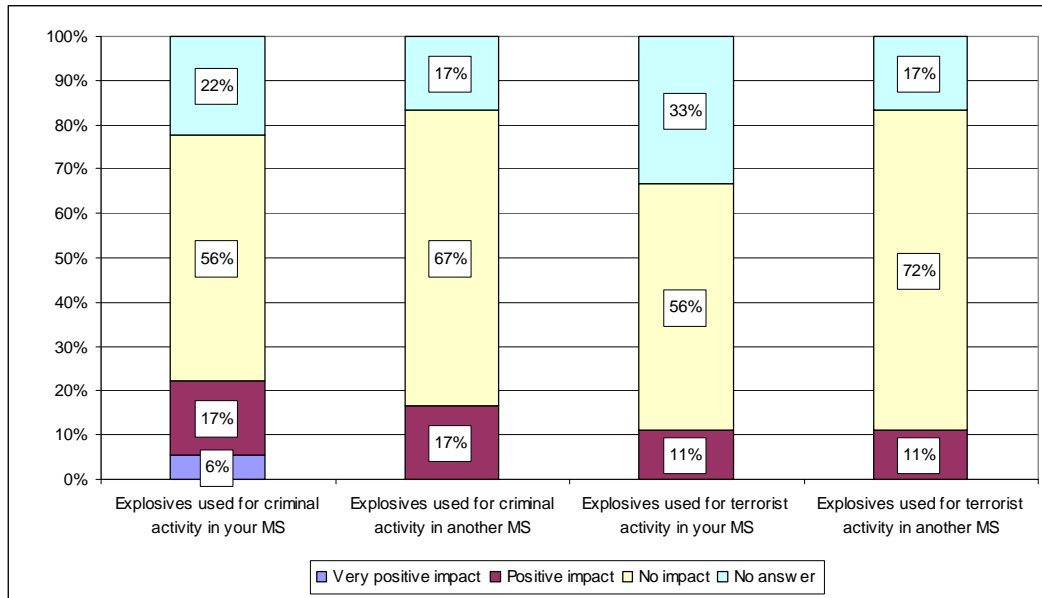
Base = 18 Competent Authorities

On a related note, the consensus amongst Competent Authorities was that the Explosives Directive has had little or no impact on security in the EU in relation to civil explosives (see Figure 3.13). Again, this was primarily since the Directive does not legislate in the field of security, beyond measures designed to harmonise supervision.

A review of the evidence on terrorist incidents in the past few years (Section 3.2.2) suggests that homemade or improvised explosive devices (which are beyond the scope of the Explosives Directive) are as much of a threat as legally manufactured civil explosives. Where civil explosives have been illegally acquired, this was a failing of national security legislation, not the Directive.

Section 1.5.2 made it clear that the depth and scope of security regulations in Member States varies substantially and that, though there is evidence of convergence, certain countries still have almost nothing in the way of minimum security standards. This is most definitely a cross-border issue (see, for instance, ETA and thefts of explosives from France), and also has implications for the operation of the Single Market (see Section 3.4.1). Indeed, it was in the area of minimum security standards that a number of consultees indicated that they would like to see EU-level intervention, either through the Explosives Directive, or through other legislation. We return to this issue in Section 4.

Figure 3.13: What impact has the Directive had on the security in the explosives industry?



Base = 18 Competent Authorities

3.5 The utility of the Explosives Directive

Utility relates to the extent to which the Explosives Directive remains fit for purpose, and, if not, what changes are needed. The recommendations of the study team – based on the results of the evaluation – are set out in the following section. There follows a review of the recommendations of the study consultees (Member States, Notified Bodies and businesses).

To start with, Competent Authorities were asked to describe the strengths and weaknesses of the Explosives Directive (Table 3.2).

Table 3.2: Strengths and weaknesses of the Explosives Directive

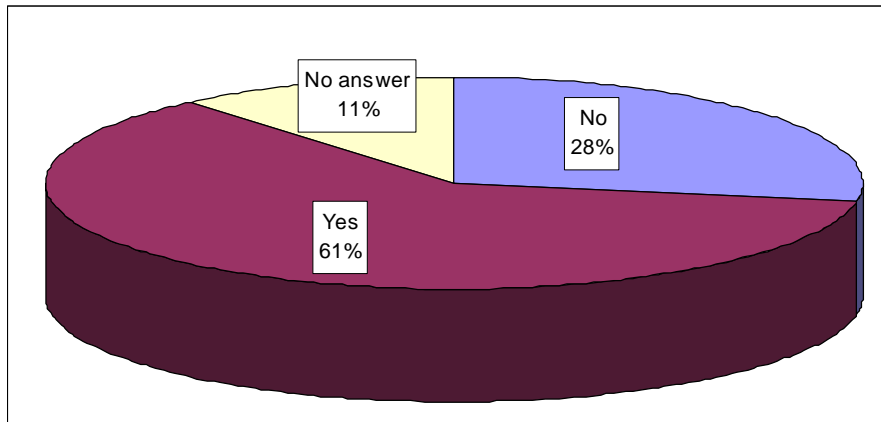
Strengths	Weaknesses
<p>The relative simplicity of the Directive;</p> <p>Harmonisation of product and process safety tests;</p> <p>The promotion of high quality standards in the manufacture of explosives;</p> <p>The CE mark framework;</p> <p>Removal of barriers to trade;</p> <p>Harmonisation of paperwork required for transporting explosives (the ICTE form);</p>	<p>The exclusion of pyrotechnical articles from the Directive²²;</p> <p>The partial coverage of ammunition in the Directive;</p> <p>There is a lack of clarity regarding protocol (eg where a product fails a Module B test);</p> <p>There is a lack of clarity regarding the conformity assessments, resulting in differences in interpretation between</p>

²² Now covered separately through Directive 2007/23/EC on the placing on the market of pyrotechnical articles.

Enhanced supervision of the cross-border transportation of explosives; Increased sharing of good practice between Member States.	Notified Bodies; The ICTE form still needs to be returned in paper form; Surveillance and tracking systems for the transport of explosives do not go far enough.
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On a related note, Competent Authorities were also asked to indicate whether the Directive brought any added value above national legislation (see Figure 3.14). The purpose was to ascertain the benefits associated with European regulation of the explosives industry, as opposed to the activities of individual Member States. The majority of respondents (61%) agreed that the Directive brought added value over national legislation, though 28% disagreed. Of the latter, the only explanation provided was that, in one Member State (Spain), the Directive was very similar to the national legislation that was in place prior to 1993. On the whole, however, Competent Authorities were keen to stress that the harmonised system of safety standards could not have been achieved through bilateral agreements between states, and that the Directive is critical to the functioning of the Single Market in explosives.

Figure 3.14: Does the Explosives Directive bring added value over existing national legislation?



Base = 18 Competent Authorities

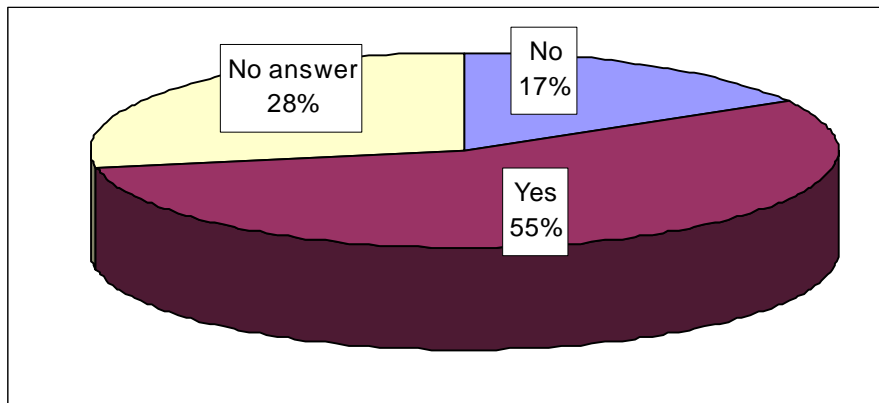
Member States, Notified Bodies and businesses were all asked whether they felt that the conformity assessment process still met the needs of the industry (or, for instance, whether technological advances meant that changes were needed). As Figure 3.15 shows, the majority of Competent Authorities (55%) felt that the tests were still appropriate, though a number felt unable to answer (28%). The Notified Bodies consulted argued that there was no need to change the scope of the conformity assessments, and furthermore that systems were in place so that any new developments would be identified and addressed by CEN. Businesses were generally satisfied, though noted a couple of areas in which the conformity assessments – or the ability of the Notified Bodies to carry out the assessments – could be improved:

- § In relation to modern electronic detonators and blasting systems one business reported that not all Notified Bodies have the technical expertise or equipment to

carry out the requisite tests (though the UK Notified Body, for example, does have such capability).

- § Another respondent suggested that CEN standards regarding black powders were in need of revision.

Figure 3.15: Does the conformity assessment process still meet the needs of the industry?



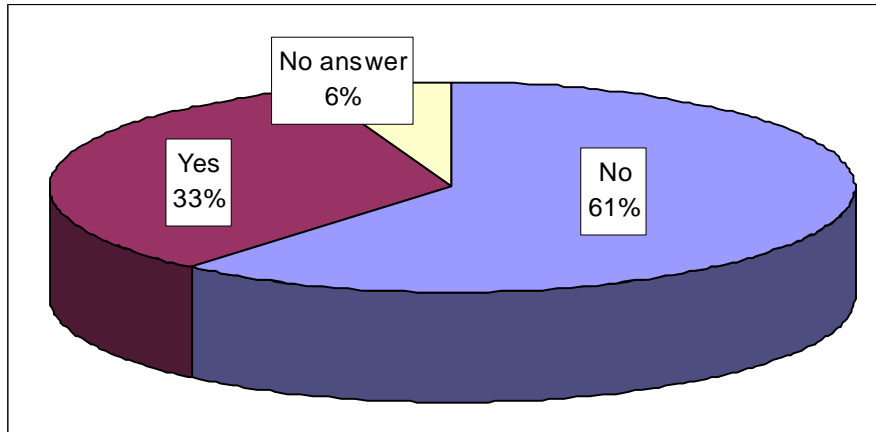
Base = 18 Competent Authorities

Finally, consultees were asked whether the Explosives Directive should be changed. Of the Competent Authorities (see Figure 3.16), the majority (61%) indicated that they were content with the current form of the Directive. A further 33%, however, felt that alterations were needed. Where information was provided, the following recommendations were made:

- § The Directive should specifically address the usage of explosives, as many national laws already do (in France, for instance). It was suggested in one instance that this might include bans or restrictions (through licences) on the usage of certain types of explosive.
- § Harmonised minimum security standards should be developed for application at all premises where significant volumes of explosives are manufactured, stored or used.
- § For bulk explosives the CE marking should be stamped on the vehicle used for transportation.
- § An identification number for Notified Bodies should be used instead of the Notified Body symbol.
- § The Directive should clarify that explosives not classified in the UN Orange Book as Class 1 cannot bear a CE marking, though one stakeholder noted that this is actually implicit within Article 1 of the Directive.
- § The online ICTE form should be made interactive so that it could be completed and submitted electronically. Another suggestion regarding the ICTE form was to remove the necessity for it to be completed for any countries other than the origin and the destination, in order to reduce the administrative burden for national authorities and businesses.

- § Clarification is needed regarding the way in which Notified Bodies carry out the conformity assessments, specifically the usage of manufacturers' tests.

Figure 3.16: Would you like to see any changes to the Explosives Directive?



Base = 18 Competent Authorities

Businesses were also asked whether the Explosives Directive should be changed. Of the ten companies who responded to the survey, five indicated that they would like to see alterations, whilst another five were content with the Directive as it currently stands. Respondents suggested the following changes:

- § Instead of only covering the 'placing on the market' of explosives, the Directive should be extended to cover the *usage* of explosives as well, in order to prevent Member States from imposing additional regulation in this area that consequently varies between authorities.
- § Improved clarity of content regarding the quality-related conformity assessments – particularly Modules C and D – to reduce the differences in interpretation between Notified Bodies.
- § An interactive online version of the ICTE form should be produced that would enable businesses to complete and upload/ email the document electronically to Competent Authorities, thus saving time.
- § A simplification of the administrative and regulatory systems within those Member States where the Explosives Directive is not being applied as intended, or where additional administrative requirements are in place that act as a barrier to trade.
- § The Directive should be extended to cover explosives manufactured on-site by MEMUs as there are currently differences in the way that national authorities regulate this area.

4 CONCLUSIONS AND RECOMMENDATIONS

4.1 The evaluation questions

Section 2.1 listed the evaluation questions. There follows a review of the conclusions of the study team with regard to each of these questions, and a series of recommendations based on these results.

How is the Explosives Directive implemented in the Member States?

The critical aspect of the Directive is the way in which Member States and Notified Bodies approach the conformity assessments. Ensuring that these are carried out to a uniform standard is crucial for safety in the industry and for the operation of the Single Market. Evidence from consultees and survey respondents indicates that the implementation of this system is not operating quite as anticipated by the Directive.

The safety standards set by CEN provide some scope for interpretation by Notified Bodies, primarily in the way in which the Module tests are carried out. Fundamentally, there is no obligation for Notified Bodies to carry out all of the tests themselves, and so a number allow the results of manufacturers' own product tests to form part or all of the assessment. There are conditions attached, and manufacturers must have undergone a Module C quality assurance 'audit' to ensure that their facilities and processes are sufficient. The cost and time savings associated with this approach make it very attractive to manufacturers. A number of Notified Bodies, however, refuse to accept the results of manufacturers' tests on safety grounds, highlighting the fact that each year a small number of products fail the conformity assessments. It appears as though the uncertainty associated with the status of manufacturers' tests has led some Competent Authorities and Notified Bodies to question the quality of conformity assessments carried out elsewhere.

Fundamentally this is a Single Market issue (see below), since the implications for safety in the industry are likely to be negligible. Manufacturers put their products through an extensive safety testing process well before they are submitted to a Notified Body to obtain a CE mark, and in some cases firms possess better testing facilities than the Notified Bodies. Though consultees pointed out that each year a small number of products fail the conformity assessments, none could identify a single occasion where a product with a CE mark had malfunctioned in a way that would implicate the Notified Body responsible for the conformity assessment. Given the nature of the industry, there is a powerful incentive for firms to ensure that their products meet all necessary safety standards, regardless of the involvement of the Notified Bodies.

The Notified Bodies were initially assessed by their respective national Competent Authorities (or by a national accreditation body) on the basis of their ability to carry out the conformity assessments in a professional and impartial way, to the necessary standard (Annex III to the Directive). After this, Competent Authorities were expected to ensure that the Notified Bodies continued to meet these requirements, though how this process was expected to work was not set out in the Directive. In reality, however, it is clear that there is very little in the way of systematic monitoring underway within the Member States. All Competent Authorities maintain that they communicate with

their designated Notified Body on a regular basis, but few go beyond this. In part this is a problem of expertise – staff at Competent Authorities rarely have the necessary technical knowledge to determine whether Notified Bodies are carrying out tests to the necessary standard. Notified Bodies almost always possess other international conformity certifications (such as ISO 9001:2000), and so the Competent Authorities tend to assume that these will be a sufficient measure of quality control. Notified Bodies also maintain an informal network of internal quality control, involving annual meetings and regular communication between all Notified Bodies and CEN. Consultees from the Notified Bodies were content that such systems would identify any cases where quality standards were no longer sufficient.

Member States have a responsibility to ensure that all explosives products on their national markets comply with the requirements of the Directive. Principally, this involves checking whether products bear a CE marking, and are accompanied by the necessary paperwork. The Directive does not specify how Member States are expected to conduct this in-market surveillance, nor does it detail protocol in the event of non-compliance (beyond an obligation to remove the product from the market). Almost all Member States implement comprehensive programmes of random inspections, covering manufacturing, storage and distribution facilities, together with sites where explosives are used. The rarity with which non-compliant products are found (only three cases have been identified since 1993) suggests that industry is almost universally complying with the requirements of the Directive. Cases of non-compliance are dealt with according to national law, and usually involve the confiscation of the products and a prison term for the offending individual(s).

Finally, in 2004 the Explosives Directive was amended to include the Intra-Community Transport of Explosives (ICTE) form. This document was introduced as a standardised template for firms seeking permission from national authorities to transport explosives through their territory, and thus was an important way in which to remove a potential barrier to trade. The ICTE form appears to be universally accepted by the Competent Authorities, though there are associated administrative costs for businesses (see below).

What are the barriers to the effective application of the Explosives Directive, if any? How could such barriers be overcome?

The main barrier to the effective application of the Explosives Directive is the different approaches adopted by the Member States towards its implementation. These have been discussed above, and centre around how Competent Authorities go about implementing the requirements of the Directive (in-market surveillance, the monitoring of the Notified Bodies), and also how they implement the Directive in parallel with their own legislation governing the explosives industry.

With regard to the former, the key problems have been reviewed above. The main issue is the fact that a small number of Member States have concerns about the quality of the conformity assessment process carried out by particular Notified Bodies. The barrier in this regard is the lack of clarity in the Directive or the standards developed by CEN about how Notified Bodies should proceed. Though this flexibility enables Notified Bodies to 'compete' by offering different kinds of service, at the same time it could be seen to call into question the uniformity of the safety testing process. This issue is discussed in more detail below. The effective application of in-market surveillance and the quality control of the Notified Bodies are dependent upon the

resourcing of the Competent Authorities. There are clearly variations between Member States in this regard, which results in some countries being much more thorough than others. The Directive, however, does not specify what needs to be done in these areas, and consequently Member States are free to prioritise such matters as they see fit.

How the Explosives Directive fits with national legislation also affects its application. To recap, national legislation governs safety and security in the industry, though in many cases laws brought in to regulate these areas also infringe on the operation of the Single Market. Many of the perceived barriers to trade (see also below) stem from national regulation regarding licensing and other administrative requirements, ostensibly introduced in order to enhance safety and security in the industry. The Italian authorities, for instance, require all documentation to be translated into Italian, primarily to improve their ability to monitor the explosives present on the national market.

Resolving these barriers would be a challenge, and would require the Directive to legislate in areas that are presently a national concern, and may well be subject to legal considerations (such as, for instance, EU-wide security standards). A key part of this could be a need for the harmonisation of licensing requirements in the industry, since variations in national approaches do affect the effectiveness of the Directive.

What have been the strengths and weaknesses of the Explosives Directive? Which parts have been more or less effective?

The strengths and weaknesses of the Explosives Directive can be summarised as follows:

Strengths	Weaknesses
<p>Safety tests have been successfully harmonised across the EU, removing a key barrier to trade.</p> <p>The mandatory application of the CE marking has ensured that all products meet these high safety standards. Non-compliance within the industry is almost unheard of.</p> <p>The technical criteria applied during the conformity assessments are determined by CEN, an independent expert body. Flexibility is thus inbuilt, and standards can be changed far quicker than if an amendment to the text of the Directive was required (which would then need to be transposed into 27 Member State laws).</p> <p>The ICTE form has made the intra-Community transport of explosives</p>	<p>There is insufficient clarity regarding the way in which the conformity assessment modules are to be carried out, resulting in variations in approach between the Notified Bodies.</p> <p>The Directive has done little to improve security in the industry, and consequently there are still a wide range of standards in operation across the EU. In addition to making the industry less secure, these variations also affect the operation of the Single Market.</p> <p>Safety also remains a largely national consideration, though the variations in minimum standards between Member States are less pronounced than for security. Again, any variations will affect the operation of the Single Market since the costs associated with compliance will</p>

<p>considerably easier, and reduced costs for businesses. Previously firms had to meet varying national requirements regarding obtaining permission to transport explosives.</p>	<p>vary.</p> <p>The ICTE form is not accessible electronically, and thus has not gone as far as it could in terms of simplifying administrative requirements.</p> <p>The scope of the Directive could be clearer; specifically, whether it only covers products placed on the market (as it does in relation to the Single Market and safety), or extends to products regardless of their status (as it does in relation to security).</p>
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In terms of which parts of the Directive have been more or less effective, the mechanisms for facilitating the development of a Single Market have generally been the most successful (see below). The conformity assessment system is, overall, operating reasonably effectively, though there are some operational problems that need to be resolved. A small number of Member States are – if not breaching the Directive outright – then certainly not applying the legislation in the way in which it was intended. There would seem to be little justification for these barriers, since they do not markedly improve industry safety in a manner proportionate to their impact on the Single Market.

The Directive aimed to increase product safety standards by harmonising testing at a high level. Other aspects of industry safety were left to national legislation. Thus it is hard to assess the effectiveness of the Directive with regard to safety, since there are key areas in which national legislation could have a more significant impact. Indeed, data would suggest that accidents in the industry are almost always a result of human error or equipment malfunction that is covered by national health and safety legislation rather than the Directive. However, without data on the number of accidents caused by faulty products before the introduction of the Directive it is hard to establish whether the legislation has had an impact or not. A lack of harmonisation in the field of national safety standards could impact on the Single Market, but since safety standards do not appear to vary significantly between Member States (licences are required everywhere, and always seem to be dependent upon certain common safety standards being met), this does not appear to be a significant problem.

The Directive contained very little in the way of requirements designed to enhance security in the explosives industry. Consequently it is difficult to assess its effectiveness or impact in this area. Overall, however, this is in itself a failing, since security is of growing importance and is very much a cross-border issue. The Explosives Directive could very well have had an impact in this area, and consultees were generally in agreement that more action was needed at the EU level, though there are issues around the legal base to act in this area (the Explosives Directive is an Article 95 piece of legislation, and thus concerns the Single Market). However, variations in national security standards affect the operation of the Single Market, and thus undermine the wider effectiveness of the Directive.

To what extent has the Explosives Directive contributed to the development of an efficiently operating internal market for explosives goods?

The limited evidence that is available suggests that there has been steady progress made towards the development of a Single Market in explosives goods, since the Directive was introduced in 1993. Firms report that the proportion of their sales derived from other EU countries grew from an average of 9% in 1993 to 15% in 2007. Trade data since 1999 indicate a slow growth in the volume and value of intra-Community exports of explosives since 1999. Almost all of the Competent Authorities surveyed agreed that the impact of the Directive on the trade in explosives has been positive. The principle barrier to trade – the varying safety standards that Member States used prior to 1993 – has been successfully removed.

However, there is also evidence that progress towards the Single Market has not been as rapid or as wide ranging as might be expected. Though we have no data for comparable sectors (dangerous goods with a need for strict regulation), most explosives manufacturers still derive the majority of their sales from domestic markets, with the exception of a few large groups of firms that have become more EU-focussed. The Single Market would also be expected to affect the international competitiveness of EU firms, yet trade data do not indicate that exports of explosives from the EU27 to the rest of the world have increased markedly in the past few years. Furthermore the key export markets for EU firms are other European states (particularly Norway, Switzerland and other Eastern European states); other than the United States, the volume of exports to key global markets is low. There may be regulatory factors to consider, but this has been beyond the scope of this study.

Consultations with stakeholders in the industry have also revealed that there are a number of barriers to trade still in place that hold back the development of a Single Market. The most important of these has been discussed above, and centres upon whether national authorities always accept the validity of CE markings awarded by Notified Bodies. This system is fundamental to the functioning of the Single Market, yet evidence from businesses and to some extent from Competent Authorities indicates that there are rare occasions where products that have legitimately been awarded a CE mark are prevented from entering another EU market. It seems that, in such cases, these products are required to undergo a full or partial retest at the Notified Body in the country where the ban has been imposed.

More common are minor administrative barriers enforced by certain countries, including requirements for certified document translation in Italy, and the paperwork associated with national law. These administrative barriers result from national safety and security requirements (primarily the latter), and importantly are not consistent across the EU. The impact of these laws on firms is particularly significant during transportation of explosives, since national security regulations in this field vary substantially. In some countries – including Spain and Bulgaria – security considerations require armed personnel to accompany any transportation. In the former, one firm reported that such movements must also be made during ‘daylight hours’. The Spanish authorities also impose additional legislative requirements on any firm wishing to import explosives that, since they would not apply to any firm purchasing explosives from a Spanish firm, create additional costs and delays where products originating from another EU country are concerned. Though perfectly acceptable according to the Explosives Directive, these requirements nevertheless go against the spirit of the operation of a Single Market.

What have been the impacts of the Explosives Directive on European companies? Has it added costs or administrative burdens?

The most significant impact of the Directive on companies has been the effect that it has had on the Single Market. As noted above, there is evidence that firms have become increasingly oriented towards EU and global markets, whereas previously most were largely focussed on meeting domestic demand. Concurrently – and probably related to this – the industry has also undergone a period of restructuring and consolidation, and a small number of large groups of companies have emerged. It is possible that these businesses have become more competitive as a result of these changes, but it has been beyond the scope of this study to examine this issue in any detail, which would require comparative consideration of international regulatory regimes and market demand.

European companies certainly face a number of administrative costs and burdens associated with the Explosives Directive. First and foremost are the costs incurred through the product conformity assessment process. Respondents estimated that on average this amounted to €5,000 per product, but where tests were particularly complex or intensive, this figure could be as high as €50,000 (though this is exceptional). The tests could also take a considerable amount of time (between 1 and 6 months according to one business), thus delaying the process through which new products (that will already have undergone a period of testing by the manufacturer or developer) are brought to market.

Notified Bodies have adopted different approaches to the conformity assessments, and by making use of manufacturers' tests a number have reduced the costs and delays associated with product safety testing. Of course, the costs associated with the previous system must have been higher, since a firm could potentially have to have a product retested for entry into each and every national market. However, it has not been possible to quantify this since no such research was undertaken back when the Directive was introduced. Furthermore the Notified Bodies are technically in competition with each other, which may have the effect of dampening the costs of the conformity assessments. Again we cannot quantify this, though it was reported by one business that, where possible, they make use of the HSL to carry out conformity assessments, since it is cheaper and quicker than other Notified Bodies as a result of using manufacturers' tests.

Firms wishing to transport explosives across EU borders also face administrative costs and burdens. The European Commission introduced the ICTE form specifically to address this problem, and there is a consensus that current arrangements are a significant improvement on the previous system. Nevertheless, completing the ICTE document and obtaining permission from each of the authorities along the route of transportation costs firms money (on average between €30 and €50 per form), and imposes delays (between two and three weeks according to one business, though this depends on the number of national authorities involved). Again, this must be taken in context. Prior to the introduction of the ICTE form, firms would have had to navigate a patchwork of different national administrative requirements, and obtain paper copies of applications direct from national authorities.

To what extent could measures be taken to improve the utility of the Explosives Directive, and what measures would these be?

This evaluation has identified the ways in which the Directive is functioning effectively, and the ways in which it has not been as successful as intended. Overall it is clear that the legislation has had a positive impact on intra-Community trade, and the system of harmonised safety testing is generally operating as intended. There is no desire amongst any of the consultees for wholesale changes to the Directive, and instead a number of minor amendments have been suggested. From these we make the following recommendations for improving the utility of the Directive:

1. **Working together with CEN, the Notified Bodies and the Competent Authorities, DG Enterprise and Industry should clarify whether manufacturers' tests should be included as part of the conformity assessment.** Provided manufacturers' testing facilities have been audited as part of the Module C test, there is a strong case for allowing these results to form part of the overall product assessment. This may not be the case for all types of explosive, but it is important that these arrangements are clarified, since the uncertainty affects the validity of the CE marking system, and acts as a barrier to trade in some instances.
2. **DG Enterprise and Industry should publish a truly electronic version of the ICTE form on its website.** The form could then be downloaded by applicants, completed, and emailed to each of the national authorities through whose territory the firm wished to transport explosives. A regularly updated list of contact details for each national authority (including an email address) would also need to be published on the DG Enterprise and Industry website. Though the approved form would need to be returned by national authorities in paper form, this nevertheless speeds up the process considerably. There is widespread support for this action amongst industry and the Competent Authorities. Alternatively a centralised databank could be created where applicants could fill in a form that would automatically be forwarded to the relevant authorities. It is understood that a system with comparable aims is currently being trialled by a small number of Member States under the AGIS Framework Programme. DG Enterprise and Industry should monitor the results of this system and consider a roll-out across the EU.
3. **On a related note, DG Enterprise and Industry should consult with industry stakeholders about whether arrangements for the intra-Community transport of explosives are necessary.** A number of businesses and a Competent Authority have queried the value of completing an ICTE form for every country on the route of transportation. It is suggested that this adds little in the way of security or safety, but does impose a considerable administrative burden on businesses. Instead, permission could only be required from the country of origin and destination. It is recommended that DG Enterprise and Industry consult further on this issue, since it is likely to be controversial with some Competent Authorities.
4. **DG Enterprise should consider whether the Explosives Directive should include a set of minimum security standards governing the civil explosives industry.** Security arrangements are very much an EU-wide concern, since explosives illegally acquired in one country could very easily make their way into a country with much tighter regulations (as has happened in the past). Given the heightened threat posed by terrorism, it would seem to be very important that security standards are raised across the EU as a matter of urgency. This would have an impact on businesses, and would be costly in countries where standards

are presently relatively relaxed. There are, however, legal implications, since the Explosives Directive is an Article 95 piece of legislation, and thus concerns the operation of the Single Market. Ultimately the Explosives Directive may not be the most suitable legislative instrument, but further debate on the issue would be beneficial.

5. **DG Enterprise and Industry should consider whether additional administrative requirements imposed by some Member States constitute a barrier to trade.** It may be necessary to clarify in the text of the Directive the paperwork that should accompany an explosive product when it crosses a border, and specifically the extent to which translation into the local language is required. It is not clear what added value these requirements bring in terms of national safety or security, yet they do cause delays to businesses and affect the operation of the Single Market.

ANNEXES

ANNEX 1: INDIVIDUALS CONSULTED DURING THE STUDY

European Commission

Laurence Cordier (European Commission – DG Enterprise and Industry)

Maik Schmahl (European Commission – DG Enterprise and Industry)

Member States

Andy Miller (UK – Health and Safety Executive)

Bernd Fischer (Germany – Federal Ministry of the Interior)

Chris Raymond (UK – Health and Safety Executive)

Christian Michaux (France – INERIS)

Dr. Dietrich Eckhardt (Germany – BAM)

François Rey (France – Ministry of Finance)

Giovanni Aliquo (Italy – Ministry of the Interior)

Jaime Ríos Vázquez (Spain – Laboratorio Oficial Jose Maria de Madariaga)

José Luis Bayona Pérez (Spain – Civil Guard)

José María Zapardiel Palenzuela (Spain – Ministry of Industry, Tourism and Trade)

Rob Duba (Netherlands – Ministry of the Environment)

Roland Wharton (UK – Health and Safety Laboratory)

Serge Miraucourt (France – Ministry of the Economy)

ANNEX 2: SURVEY RESPONDENTS

Member States

Ago Pelisaar (Estonia – Ministry of Economic Affairs and Communication)

Anders Nilsson (Sweden – SP Technical Research Institute of Sweden)

Andy Miller (UK – Health and Safety Executive)

Anthony Camilleri (Malta – Malta Standards Authority)

Attila Kovacs (Romania – INSEMEX-SECENTI)

Constantin D. Ciocoiu (Romania – INSEMEX-SECENTI)

Dominique Corbaye (Belgium – Ministry of Economy and Energy)

Egon Hirvesoo (Estonia – Technical Inspectorate)

Erotokritos Anastassiades (Cyprus – Mines Service)

Frédéric Davous (France – Home Office)

Giovanni Aliquò (Italy – Ministry of the Interior)

Johan van Ee (Netherlands – Ministry of the Environment)

José Luis Bayona Pérez (Spain – Civil Guard)

José María Zapardiel Palenzuela (Spain – Ministry of Industry, Tourism and Trade)

Karin Baunsgaard (Denmark – Ministry of Justice)

Michel Ropers (France – Home Office)

Mirosław Kurek (Poland – Ministry of Economic Affairs)

Otto Kysela (Czech Republic – Czech Mining Authority)

Pierre-Marie Fromenteau (France – Home Office)

Rajko Pušnik (Slovenia – Ministry of the Interior)

Rob Duba (Netherlands – Ministry of the Environment)

Robert Huberty (Luxembourg – Mines Labour Inspectorate)

Sérgio Nunes (Portugal – Polícia de Segurança Pública)

Tapani Koivumäki (Finland – Ministry of Trade and Industry)

Tudoric• Constantin-Lucian (Romania – Ministry of Labour, Family and Equal Opportunities)

Violina Panayotova (Bulgaria – State Agency for Metrological and Technical Surveillance)

Businesses

Ashley Haslett (Managing Director, Ulster Industrial Explosives Ltd)

Eoin Bartley (Commercial Manager, Irish Industrial Explosives Ltd)

Hans H. Meyer (General Manager, Orica Germany GmbH)

Jean-Paul Reynaud (Technical and HSE Manager, Nobel Explosifs France)

John Simms (Logistics and Procurement Manager, Exchem Explosives Ltd)

Manfred Dax (Company Manager, Sprewa Sprengmittel GmbH)

Margarida da Silva Vieira (Moura Silva & Filhos, S.A.)

Dr. Martin Held (Westsprenng GmbH)

Otta Greben (Marketing Director, Austin Detonator)

Ramón G. Eguren (Quality & Security Manager, MaxamCorp, S.A.U.)

3) Please list any **other** legal requirements that your Member States has in relation to the manufacture, storage or transport of explosives that are not part of the Explosives Directive. (perhaps relating to industry safety)?

Please provide details and explain why these are needed in the box below. Please be clear whether these are supplementary to the requirements of the Directive, or whether they contradict the Directive. Please also indicate whether these requirements are mandatory or voluntary.

4) Have any infringement proceedings been brought against your Member State regarding the application of the Explosives Directive by the Commission or by a European company?

No (please go to question 5)

Yes (please fill in the following table)

Year	Details of proceedings (eg legal case)	Result of proceedings	Actions resulting from the proceedings (eg amendments to law)

5) Please indicate the number of safety tests (as set out in the Directive) that your Member State has carried out (for as many years as data are available).

Year	Module B		Module C		Module D		Module E		Module F		Module G	
	No. done	No. failed	No. done	No. failed	No. done	No. failed	No. done	No. failed	No. done	No. failed	No. done	No. failed
2006												
2005												
2004												
...												

6) Please describe in the box below the process through which your organisation checks whether explosives products on the market bear a CE Marking.

7) Have explosives products ever been found on the market in your country that did not bear the CE Marking? If so, what action did your organisation take to resolve this?

No (please go to question 8)

Yes (please fill in the following table)

Year	Action taken

SECTION 2: THE EFFECTIVENESS OF THE EXPLOSIVES DIRECTIVE

8) With the Directive in place, are there any remaining constraints on the free movement of explosives products between Member States in the EU?

No (please go to question 9)

Yes (please describe these in the box below)

9) In your opinion does the safety testing process (Module B, C etc) ensure that the manufacture and use of explosives products is safe?

Yes No If no, please explain your answer

Manufacture of explosives

<input type="checkbox"/>
<input type="checkbox"/>

<input type="checkbox"/>
<input type="checkbox"/>

Use of explosives

10) In your opinion does the Directive ensure that the transport of explosives is safe?

No (please indicate why you think this is the case in the box below):

Yes (please go to question 11)

11) In your opinion, do the measures in the Directive designed to improve security systems in the explosives industry work effectively?

No (please indicate why you think this is the case in the box below):

Yes (please go to question 12)

12) Please indicate what you consider to be the strengths and weaknesses of the Explosives Directive in the box below:

Strengths of the Directive	Weaknesses of the Directive

SECTION 3: THE IMPACT OF THE EXPLOSIVES DIRECTIVE

13) What impact has the Directive had on improving safety in the explosives industry in the EU, in respect of the manufacture, transport and use of explosives products?

Manufacture	<input type="checkbox"/>	Very positive impact	<input type="checkbox"/>	Positive impact	<input type="checkbox"/>	No impact	<input type="checkbox"/>	Negative impact	<input type="checkbox"/>	Very negative impact
Transport	<input type="checkbox"/>	Very positive impact	<input type="checkbox"/>	Positive impact	<input type="checkbox"/>	No impact	<input type="checkbox"/>	Negative impact	<input type="checkbox"/>	Very negative impact
Use	<input type="checkbox"/>	Very positive impact	<input type="checkbox"/>	Positive impact	<input type="checkbox"/>	No impact	<input type="checkbox"/>	Negative impact	<input type="checkbox"/>	Very negative impact

Please explain your answers in the box below, providing evidence if possible (eg number of industrial accidents):

14) What impact has the Directive had on improving security in respect of explosives in the EU?

Explosives used for criminal activity in your Member State	<input type="checkbox"/>	Very positive impact	<input type="checkbox"/>	Positive impact	<input type="checkbox"/>	No impact	<input type="checkbox"/>	Negative impact	<input type="checkbox"/>	Very negative impact
Explosives originating in your country used for criminal activity in other Member States	<input type="checkbox"/>	Very positive impact	<input type="checkbox"/>	Positive impact	<input type="checkbox"/>	No impact	<input type="checkbox"/>	Negative impact	<input type="checkbox"/>	Very negative impact

Explosives used by terrorists in your Member State	<input type="checkbox"/>	Very positive impact	<input type="checkbox"/>	Positive impact	<input type="checkbox"/>	No impact	<input type="checkbox"/>	Negative impact	<input type="checkbox"/>	Very negative impact
Explosives originating in your country used by terrorists in other Member States	<input type="checkbox"/>	Very positive impact	<input type="checkbox"/>	Positive impact	<input type="checkbox"/>	No impact	<input type="checkbox"/>	Negative impact	<input type="checkbox"/>	Very negative impact

Please explain your answers in the box below, providing evidence if possible (eg number of instances when explosives have been stolen, number of instances when explosives have been illegally used in your Member State):

15) What impact has the Directive had on increasing the amount of cross-border trade in explosives products within the EU (the creation of a Single Market)?

<input type="checkbox"/>	Very positive impact	<input type="checkbox"/>	Positive impact	<input type="checkbox"/>	No impact	<input type="checkbox"/>	Negative impact	<input type="checkbox"/>	Very negative impact
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Please explain your answer in the box below, providing evidence if possible (eg trade information):

16) What impact has the Directive had on innovation in the explosives industry?

Very positive impact

Positive impact

No impact

Negative impact

Very negative impact

Please explain your answer in the box below, providing evidence if possible:

17) Has the administration of the Directive imposed any substantial costs on your organisation?

No (please go to question 18)

Yes (please provide details and quantify if possible):

18) Has the Directive imposed significant additional administrative costs or burdens on businesses in your Member State?

No (please go to question 19)

Yes (please provide details and quantify if possible):

SECTION 4: THE UTILITY OF THE EXPLOSIVES DIRECTIVE

19) Does the Explosives Directive bring any additional benefits over existing legislation in your Member State?

No (please explain your answer in the box below):

Yes (please explain your answer in the box below):

20) Do the safety tests still meet the needs of the industry (for example, do technological advances mean that changes are needed)?

No (please explain your answer in the box below):

Yes (please proceed to question 21)

21) Would you like to see any changes made to the Explosives Directive?

No

Yes (please provide details in the box below and explain why this would make the Directive more effective):

22) Is there anything else you would like to add that has not been included in this survey?

Many thanks for your assistance

ANNEX 4: THE BUSINESS SURVEY

GHK has been commissioned by the European Commission to evaluate the effectiveness and impact of Council Directive 93/15/EEC (the Explosives Directive). The Directive will have been transposed into national law in your country and so you may not recognise it as a European piece of legislation, but the survey has been designed to only address issues affected by the Explosives Directive.

As part of the study we are surveying all of the major explosives firms in the EU in order to investigate their views on:

- § Whether the Directive has enabled the development of the Single Market in explosives in the EU;
- § Whether the system of safety tests is operating effectively;
- § The costs of the administrative requirements on businesses.

We would be very grateful if you could spare 20-25 minutes to complete this survey. Your answers will be treated in strictest confidence and will not be passed on to any third party – including the European Commission – in a form that will enable the identification of individual businesses.

Please note that this survey has been sent to all individual explosives companies in the EU – including individual firms that are part of a larger group. Please only provide answers in respect of your company not for the group as a whole.

Please also note that the Directive only covers explosives for civil use (not by police forces or the military) and does not cover pyrotechnics (fireworks etc), so please exclude these areas from your response.

YOUR CONTACT DETAILS

Name:	Name of company:	Title/Department/Organisation:
E-mail address:	Telephone number:	

DETAILS ABOUT YOUR BUSINESS

1) How many people are employed in your company *in your country* (ie including all sites in your country, but excluding those in overseas operations)?

2) Please indicate in the following table which activities your company is involved in (you may tick more than one box):

	Propellants	Prepared explosives	Fuses, detonators etc.
Manufacture of raw materials/ components			
Manufacture of finished products			

3) If your company is engaged in any other relevant activities, please describe these in the box below:

4) If your company manufactures prepared explosives, please list which ones in the following box:

THE SINGLE MARKET IN CIVIL EXPLOSIVES

5) Please estimate the **percentage** of your sales that are generated in the following markets:

In 1993 (or, if later, the earliest year for which information is known):

<input type="text"/>	National	<input type="text"/>	EU	<input type="text"/>	Other Europe	<input type="text"/>	Other
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At the present:

<input type="text"/>	National	<input type="text"/>	EU	<input type="text"/>	Other Europe	<input type="text"/>	Other
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6) Since 1993 (or, if later, the earliest year for which information is known) would you say that the **volume of units** of explosives products that your company exports to other countries in the EU has:

<input type="text"/>	Increased significantly?	<input type="text"/>	Increased?	<input type="text"/>	Remained the same?	<input type="text"/>	Decreased?	<input type="text"/>	Decreased significantly?
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Please explain why this has been the case in the following box:

7) If there are any significant trends in the volume of exports to other countries in the EU of **particular products** (eg ANFO, emulsions etc), please describe and explain these in the box below:

8) If there are any significant trends in the volume of exports to **particular countries** in the EU, please describe and explain these in the box below:

9) In your opinion, are there currently any barriers or obstacles that hinder your company's exports of explosives to other EU countries?

Yes No

If you answered yes, please complete the following table (you may tick more than one box):

	Competitive reasons (eg costs lower in other countries)
	Market reasons (eg lack of demand for products)
	Logistical reasons (eg the practicality of transporting explosives over long distances)
	Administrative reasons (eg time taken to complete the necessary paperwork and receive authorisation)
	Regulatory or legislative barriers in your own country (please answer question 10)
	Regulatory or legislative barriers in other countries (please answer question 11)
	Other factors (<i>please specify in the following box</i>):

10) If you think that there are **regulatory or legislative** barriers in your own or other countries that impede the free movement of explosives products within the EU, please complete the following table:

Barrier	Applicable country(s)	Effect on your operations

11) Have you informed anybody about these barriers, and, if so, why have these barriers not been removed?

Barrier	Organisation(s) informed (eg European Commission, the Government in your country)	Why has this barrier not been removed?

SAFETY TESTING AND THE DIRECTIVE

12) Please indicate how many of each type of safety tests your company has had carried out in the past few years:

	Module B (EC type examination)	Module C (type conformity)	Module D (production quality assurance)	Module E (product quality assurance)	Module F (product verification)	Module G (unit verification)
2006						
2005						
2004						
...						

13) Apart from the mandatory Module B test, how do you choose which Module test to carry out on a product?

14) Please indicate the average cost (in Euro) associated with these safety tests:

Per year
 Per product

15) Do you consider these costs to be:

Too high? About right?

16) In your opinion, should the safety tests be changed?

No (please proceed to question 17) Yes (*please describe these changes in the box below and indicate why they would be an improvement*)

17) Please indicate **how many** safety tests you have had carried out at each of the Notified Bodies in the EU (please add together data for all years for which information is available):

	Module Test					
	B	C	D	E	F	G
Institut National De L'environnement Industriel Et Des Risques (INERIS) (<i>France</i>)						
Laboratorio Oficial Jose Maria De Madariaga (<i>Spain</i>)						
TNO Certification (<i>Netherlands</i>)						
Health and Safety Laboratory (<i>UK</i>)						
Bundesanstalt Für Materialforschung Und Prüfung (BAM) (<i>Germany</i>)						
SP Sveriges Tekniska Forskningsinstitut AB (<i>Sweden</i>)						
Główny Instytut Górnictwa (GIG) (<i>Poland</i>)						

	Module Test					
	B	C	D	E	F	G
Centre De Contrôle De Carnelle ASBL (<i>Belgium</i>)						
Finnish Defence Forces Research Institute Of Technology (<i>Finland</i>)						
VVUU AS (<i>Czech Republic</i>)						
Konstrukta-Defence JSC (<i>Slovakia</i>)						
Other (please name)						
Total						

18) Please rank in terms of importance the reasons for your choice of Notified Body (where 1=most important reason):

Rank

<input type="text"/>	Proximity to the site of manufacture
<input type="text"/>	Cost of the safety test
<input type="text"/>	Quality of the safety test as a whole
<input type="text"/>	Quality of a particular Module
<input type="text"/>	Other (<i>please describe in the following box</i>):

19) In your experience, are the results of the safety tests carried out by the Notified Bodies accepted throughout the EU?

<input type="checkbox"/>	Yes (please proceed to question 20)	<input type="checkbox"/>	No (<i>please indicate which Member States have not accepted the results of a test, and the Notified Body</i>):
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THE CROSS-BORDER TRANSPORTATION OF EXPLOSIVES PRODUCTS

20) Has your company ever had to transport explosives products across a national border within the EU?

Yes No (please proceed to question 26)

21) Did you make use of the European Commission's online Intra-Community Transfer of Explosives Document?

Yes No (please proceed to question 23) I am unaware that it exists (please proceed to question 23)

22) In your experience is this Document accepted throughout the EU?

<input type="checkbox"/>	Yes
<input type="checkbox"/>	Yes, though additional information was required (<i>please indicate which countries, and what this information included</i>):
<input type="checkbox"/>	No (<i>please indicate which countries refused to accept the Document, and why</i>):

23) Please can you estimate the administrative costs (per transaction) associated with the cross-border transportation of explosives products in the EU (eg time taken to complete the form, associated delays, need to employ extra staff etc.)

24) Do you consider these costs to be:

Too onerous? About right?

25) In your opinion, should the administrative requirements for transporting explosives products across national borders within the EU be changed?

No (please proceed to question 26) Yes (*please describe these changes in the box below and indicate why they would be an improvement*)

OTHER ISSUES

26) What impact has the Directive had on innovation in your business?

Very positive impact Positive impact No impact Negative impact Very negative impact

Please explain your answer in the box below:

27) Has the Directive kept up with technological changes in the explosives industry?

Yes (please proceed to question 28)

No (please explain your answer in the following box):

28) Would you like to see any changes made to the Explosives Directive?

No (please proceed to question 29)

Yes (please describe these changes in the box below and indicate why they would be an improvement)

29) Is there anything else you would like to add that has not been included in this survey?

Many thanks for your assistance

ANNEX 5: MEMBER STATE CASE STUDIES

France

The explosives industry in France

France is a significant consumer and producer of explosives, and is home to a number of important firms including Nobel Explosifs, Titanite, and Davey Bickford. Explosives are particularly important in the French construction industry.

The wider legislative environment in France

In addition to the Explosives Directive there are other pieces of domestic legislation governing safety and security in the explosives industry. The main safety and security requirements regarding explosives are provided by Decree n°81-972 and Decree n° 90-153.

Safety

In France a licence is required in order for a business to manufacture or store explosives. The licence (*demande d'agrément technique*) is granted by the local authority (prefect), based on the submission of a dossier detailing measures that will be taken to prevent accidents from occurring, and on consultation with the local police force and the regional directorate for industry. The acquisition of explosives – to store, transport or use – is also dependent upon authorisation from the prefect, and the certificate is only valid for one year.

Security

Security related legislation in France has become considerably stricter in the past few years, in response to the threat posed by international terrorism. In 1999 members of ETA stole dynamite from a warehouse in Plévin, Brittany, prompting a tightening of regulation governing the storage of explosives. In December 2005 three separate laws (*Arrêtés*) were passed that further strengthened security requirements for premises where explosives are manufactured or stored. Measures include a secure perimeter, interior alarm and detection systems, and 24-hour surveillance. Moreover, businesses are also required to undergo a security assessment (*études de sûreté*) by an accredited external body (usually an independent risk assessment and safety testing company), the results of which must be authorised by regional government. Where changes are required, these must be monitored by the same external body. This assessment is only valid for five years, after which it must be carried out again.

The application and implementation of the Explosives Directive in France

There are a number of government departments responsible for the implementation of various aspects of the Explosives Directive. The Competent Authority with overall responsibility for the implementation of the Directive in France is the Ministry of the Economy. Within the Ministry the Directorate for Enterprise deals with safety issues concerning explosives. Security is dealt with by the Ministry of the Interior, within which the Directorate of Public Liberties and Legal Affairs has responsibility for issues involving the prevention of crimes inside an explosives factory or storehouse.

Conformity assessments and the Notified Body

French authorities reported that they always accept the results of a conformity assessment, regardless of which Notified Body carried out the test. Generally, consultees felt that the system worked well, though there were occasional 'misunderstandings' between Competent Authorities and businesses over CE markings. On the whole, however, these were seen to be rare occurrences, and were always resolved speedily.

The Notified Body in France is the National Institute for Industrial Risks and Environment, or INERIS. The Institute was initially established to carry out tests for the mining industry, but over time has evolved to work with all types of civil explosives. INERIS is a very large organisation with considerable technical expertise. The following table provides data on the number of conformity assessments carried out by INERIS between 2004 and 2006 (unfortunately data on the number of failures are not available).

Year	No. of Module C tests carried out	No. of Module D tests carried out	No. of Module F tests carried out	No. of Module G tests carried out
2006	4	5	2	3
2005	17	32	6	0
2004	7	58	5	0
<i>All years</i>	<i>28</i>	<i>95</i>	<i>13</i>	<i>3</i>

Source: INERIS²³

The method of approach adopted by INERIS towards the conformity assessments is flexible, and is decided on a case-by-case basis. In many instances INERIS carries out all of the tests in-house, but in other cases it also makes use of the results of tests carried out by manufacturers. A consultee at INERIS indicated that many of the large manufacturers have the technical testing capacity to conduct tests at an equal or even higher standard than that carried out by the Notified Body (particularly where the product is technologically advanced). In these cases, provided the manufacturer has undergone an audit to prove that they have the necessary capability (audits are carried out by INERIS), then it is seen as cost effective to allow manufacturers' tests to form part of the conformity assessments. It was suggested that this approach sits between the Notified Body in the UK (the HSL) where this method of is routine, and LOM in Spain, where manufacturers' test results are never used.

Ongoing quality control of the Notified Body

Quality control in France is relatively systematic. Twice a year a steering committee (*Comité de Pilotage*) supported by the Ministry of the Economy conducts a detailed assessment of the tests carried out by INERIS. In addition to this activity, Notified Bodies effectively monitor each other through annual meetings and knowledge sharing arrangements. Consultees indicated that the approaches taken by INERIS towards the conformity assessment are well known to other Notified Bodies (and vice versa), because of this ongoing system of information exchange.

In-market product surveillance

²³ http://www.ineris.fr/index.php?module=cms&action=getContent&id_heading_object=169

In-market product surveillance in France is organised by the Ministry of the Economy. Every year the Ministry publishes an annual inspection plan (*Plan de Prélèvement*) that is implemented by its regional directorates – *Directions Régionales de l'Industrie, de la Recherche et de l'Environnement*. The annual total budget for inspections is around €100,000. On average 12 premises where explosives are manufactured, stored and used are inspected each year, usually at random, but on occasions in response to notification of a possible breach of the law. Activities include checks to ensure that all products bear a CE marking, and also a small number of product tests to verify conformity.

Overall the level of infraction is very low. Consultees reported that they could not identify any instances in the past years where an explosives product was been found on the French marketplace that did not comply with the Directive. This low level of infraction is believed to reflect a high level of compliance, rather than insufficient in-market checks. It was reported that the explosives industry in France is dominated by a small number of large firms that are experienced in the industry, know the rules very well, and have regular contacts with the authorities.

The Intra-Community Transfer of Explosives Document

In general the French authorities are satisfied with the operation of the ICTE form. However, the Directive specifies that the national authorities must take measures to ensure that the document cannot be falsified, and also that it is suitably robust to resist tearing or creasing during normal use. In order to satisfy these requirements, in France it has been decided that blank forms must be obtained from authorised printers linked with the National Printing House (*Imprimerie Nationale*). Consequently, firms cannot make use of the form available on the DG Enterprise and Industry website, and must still obtain a paper copy for completion.

Key findings

The main points of note from the case study of the Explosives Directive in France are:

- § Domestic legislation governing safety and security is relatively strict, though in the latter case this is a result of recent regulation passed in response to the threats posed by terrorism.
- § The French authorities report that they always accept the results of conformity assessments carried out by Notified Bodies.
- § INERIS has adopted a relatively flexible approach to conformity assessments, in many cases utilising the results of manufacturers' tests, where the facilities have been audited.
- § The Ministry of the Economy carries out checks on the ability of INERIS to undertake conformity assessments twice a year. Alongside this there is an informal network of quality control in operation between the Notified Bodies.
- § In-market surveillance in France takes place systematically, yet has not identified any instances where a product has been found to be seriously in breach of the Directive. It is thought that this is a reflection of the fact that the explosives industry in France is dominated by large, experienced firms that are well known to the authorities.

Germany

The explosives industry in Germany

Germany is one of the largest producers and consumers of explosives in the EU. There are two very large firms manufacturing high explosives – Orica and Westspreng GmbH – together with a handful of other smaller producers manufacturing high explosives, detonators and igniters, and other explosives products. The principle domestic market is the mining industry, together with quarrying, civil engineering, and the manufacturing sector (including propellants for airbags in vehicles).

The wider legislative environment in Germany

In Germany the domestic civil explosives industry is regulated by the Explosives Law. Under this legislation, a licence is required for any firm wishing to manufacture, store, transport or use civil explosives. The licence is dependent upon a number of safety and security related considerations, including the ability of the applicant to prove that they have the necessary specialist technical knowledge and expertise to work with explosives, and consideration of their 'reliability'. Background checks are carried out on applicants (including whether they have a criminal record and whether they have been a member of extremist political parties), and a register of licensees is held by the intelligence services.

There are also a number of safety and security requirements that premises where explosives are manufactured, stored or used must meet. A licence is required for any firm wishing to transport explosives in Germany and is again dependent upon a set of safety and security conditions, including a background check on the applicant. Firms from other EU countries wishing to transport explosives in Germany do not have to have obtained this licence (though an ICTE form is required), but there must be somebody present during transit who has a licence.

These domestic measures are in place in order to ensure that the explosives industry in Germany is both safe and secure. The German authorities indicated that they do not believe that domestic legislation acts as a barrier to trade, and that the costs to businesses associated with compliance are relatively minimal, certainly compared to a number of other EU countries with much stricter national law (such as Spain and Italy).

The application and implementation of the Explosives Directive in Germany

The Competent Authority responsible for the implementation of the Explosives Directive in Germany is the Federal Ministry of the Interior.

Conformity assessments and the Notified Body

The Notified Body in Germany responsible for carrying out the conformity assessments is the Bundesanstalt für Materialforschung und Prüfung (BAM) – a government funded testing facility with considerable experience of working with explosives. BAM carry out large numbers of conformity assessments tests each year (between 150 and 200 Module B assessments, and between 10 and 20 Module C and D assessments).

In almost every case, BAM insists on carrying out the entire assessment itself, and does not make use of the results of manufacturers' tests. A representative from BAM

argued that this approach is needed in order to ensure that products are independently assessed. Each year a small number of samples (between 2 and 8) fail the conformity assessment process; if such tests were left to manufacturers then these products would have been given a CE marking. On rare occasions BAM does allow manufactures to carry out their own tests, but only where specialist equipment is needed (such as the recreation of the environment of a coal mine), and in each case an individual from BAM must be present to supervise.

The German authorities report that, though they have concerns about the use of manufacturers' tests as part of the conformity assessment process, they never question the validity of a CE mark on a product. Instead, it was suggested that the main barrier to the operation of the Single Market is the additional paperwork required by some Member States, in particular Italy. In Italy the authorities insist that any firm wishing to export products into Italy must provide, in Italian, the entire test report, whereas the Directive only obliges firms to provide the results of the test report. This requirement causes delays and imposes additional costs on firms wishing to place products on the Italian market.

Ongoing quality control of the Notified Body

BAM was initially assessed by the Federal Ministry of the Interior in order to ensure that it was capable of carrying out the conformity assessments. Each year BAM submits a short report to the Ministry indicating how many tests have been carried out under each Module, and also reporting on any other issues that have emerged. Moreover, it was reported that there is regular communication between the two organisations that would quickly identify any problems.

In-market product surveillance

In-market surveillance is coordinated centrally by the Federal Ministry of the Interior. The checks are carried out by authorities in the 16 länder, who visit manufacturing and storage facilities, as well as sites where explosives are used, in order to ensure that products bear a CE mark and are labelled correctly. In the event of non-compliance the länder are required to inform the Competent Authority, though since the Directive was introduced in 1993 it is not thought that there has been a single instance where a product was found not to have a CE marking (though there have been a small number of labelling problems – between 5 and 10 since 1993). Overall the authorities report that the explosives industry in Germany is made up of a small number of firms with many years of experience. Competition in the industry is such that any firm producing faulty products would quickly be identified.

The Intra-Community Transfer of Explosives Document

The ICTE form was introduced in Germany in 2004, though it was suggested that it was identical to previous domestic arrangements. Overall consultees indicated that the document had made it considerably easier for firms to transport explosives across EU borders, and that no problems had been reported to the German authorities. However, the lack of an electronic system of submission and approval was seen to be a cause of delays for businesses. To solve this problem the authorities reported that they are working with five other Member States to pilot an IT system, funded under the AGIS Framework Programme of the EU.

Key findings

The main points of note from the German case study are:

- § Safety and security in the explosives industry are largely regulated by national legislation;
- § The German authorities report that they always accept the validity of a CE marking, regardless of where the product was tested;
- § BAM almost always carry out the entire conformity assessment in-house, and only rarely permit manufacturers' tests to form part of the assessment (and only under supervision);
- § It was reported that some Member States place additional demands on firms in respect of the paperwork needed for entry onto their national market;
- § In-market surveillance is relatively thorough, and has never identified an instance of non-compliance.

Italy

The explosives industry in Italy

The explosives industry in Italy is relatively small and centred upon quarrying and civil engineering. Key firms include Pravisani S.p.A and Sipe Nobel S.r.l.

The wider legislative environment in Italy

In addition to the Explosive Directive there are other pieces of domestic legislation establishing rule on safety and security of the explosive industry in Italy.

Safety

Anybody wishing to manufacture, store, transport or use explosives in Italy must obtain a licence from the authorities. These licences are dependent upon the applicant meeting certain safety standards, including requirements for the minimum distance between the site in question and any inhabited buildings or pieces of infrastructure (roads, pipelines, electricity pylons etc). The transportation of explosives must also meet safety criteria regarding the nature of the vehicle, and must also be accompanied by an escort.

Security

Security in the explosives industry in Italy is regulated by the Framework Law on Public Order and Security. Requirements are relatively strict, and have largely been developed in response to the threat posed by the Mafia (there were a number of incidents in the 1990s where explosives were stolen and used for criminal activity), and more recently from threats posed by international terrorist groups. A licence from the Ministry of the Interior and/or the police is required for anyone wishing to manufacture, store, import, transport or use explosives, and this is only granted provided certain security standards are met (such as 24-hour surveillance of the establishment for which the application is made). The police usually carry out an inspection of the facility in question, and also a background check on the applicant before a licence is granted. The police also require notification if explosives are to be transported, and this can only be carried out where there is a 'genuine need'.

The application and implementation of the Explosives Directive in Italy

The Competent Authority responsible for the implementation of the Explosive Directive in Italy is the Ministry of Interior. The police are responsible for undertaking inspections of premises and enforcing security related aspects of national legislation.

Conformity assessments and the Notified Body

There is no Notified Body in Italy, and instead Italian manufacturers must send products abroad in order to obtain a CE marking.

In-market product surveillance

In Italy, since 2005 all facilities where explosives are manufactured, stored or used are inspected annually. Sites where explosives are used are inspected twice a year. Further inspections are carried out randomly, though the authorities also conduct surveillance based on requests from sub-national government.

In 2006 an unlicensed factory was discovered to be manufacturing black powder without a CE marking. The black powder was seized, the factory closed and the owner arrested. According to the Italian legislation the illegal production of explosives is a criminal offence (punishable by up to six years of prison plus administrative sanctions). This has been the only case in which explosive were found without the CE marking.

The Intra-Community Transfer of Explosive Document

In Italy all explosives, even those coming from another Member State, have to bear a CE marking with accompanying paperwork in Italian (a certified legal translation is needed). In addition, further information is required regarding the explosive product, including a detailed description of the type of explosive.

A request for permission to transport explosives has to be submitted to the Ministry of the Interior. Consultees from the Italian authorities report that it normally takes between one and ten days to obtain the permission. The Ministry of the Interior uses this information to maintain a database of all explosives present on the Italian market, nominally in order to increase security by enabling them to track where explosives are located. However, consultees reported that the information submitted through the ICTE form is not sufficient to enable the thorough monitoring of the industry, and the fact that it is paper-based rather than electronic is inefficient.

Key findings

The main points of note from the case study of the Explosives Directive in Italy are:

- § The explosives industry in Italy is tightly regulated through national safety and security legislation.
- § Licences are required for most activities within the explosives industry, and these are only granted provided certain safety standards are met. Licences are also dependent on conformity with a number of security related requirements, most put in place in response to the criminal threat posed by the Mafia.
- § In-market surveillance is relatively thorough, and Italy is one of the few countries to have found non-compliant products on the marketplace.
- § Of all of the case study countries, Italy is the only one without a domestic Notified Body. This increases the costs and delays associated with conformity assessments by Italian firms, and also for other firms, since being able to use an Italian Notified Body would overcome some of the problems associated with the paperwork requirements of the Italian authorities (see the next bullet point).
- § The Italian authorities require more in the way of paperwork than most other countries. Anybody wishing to transport explosives into the country must provide the authorities with detailed information regarding the product – with a certified translation into Italian. These details are required in order to enhance monitoring and security, and indeed the authorities feel that the requirements of the Directive in this respect do not go far enough.

The Netherlands

The explosives industry in the Netherlands

The consumption of explosives in the Netherlands takes place on a very small scale, primarily through the construction industry and as part of quarrying activity. Consequently there is little in the way of a domestic explosives production industry (the largest firm is Muiden Chemie BV).

The wider legislative environment in the Netherlands

In addition to the Explosives Directive there are other pieces of domestic legislation governing safety and security in the explosives industry.

Safety

In the Netherlands, a licence granted by the Ministry of the Environment is required for firms wishing to manufacture, store or use explosives. The licence is dependent on the business fulfilling a number of health and safety related criteria, including the level of noise and air pollution, and the minimum distance between the site in question and residential properties or other work premises.

Security

In the Netherlands there are currently no specific security requirements, and arrangements are instead left to the discretion of the individual premises. In the next year or so, security arrangements in the Netherlands will become much stricter as laws come into force that stipulate minimum security standards, detail recommended training for employees of the explosives industry, and also establish protocol in the event of employee kidnapping, armed raids etc.

The application and implementation of the Explosives Directive in the Netherlands

The Competent Authority responsible for the implementation of the Explosives Directive in the Netherlands is the Ministry of the Environment. Within the Ministry there is an Inspectorate Service responsible for ensuring that individuals and companies adhere to relevant domestic legislation and the Explosives Directive.

Conformity assessments and the Notified Body

The Competent Authority in the Netherlands reported that they always accept the validity of a CE marking, regardless of which Notified Body had carried out the conformity assessment. A representative from the Ministry of the Environment noted that there was a perception that this was not the case with all Member States, but that they had no specific evidence about the scale of the problem.

The Notified Body in the Netherlands is TNO Certification, an independent research facility that specialises in testing and certifying industrial products (including explosives, medical devices and radio devices). Unfortunately no data have been provided on the number of conformity assessments carried out by TNO Certification, nor have any of the businesses that responded to the survey reported that they had employed the organisation to undertake product tests.

Ongoing quality control of the Notified Body

There is no formal system through which the Ministry of the Environment monitors the ability of TNO Certification to undertake the product conformity assessments. The Notified Body was initially certified by the Competent Authority and there is regular communication between the two organisations, but a representative from the Ministry of the Environment reported that they do not have the necessary technical expertise to carry out checks. Instead it was noted that the Notified Bodies effectively 'police' themselves through an informal quality control network (including annual meetings), during which any problems with an individual organisation would become apparent.

In-market product surveillance

Prior to 2007, the Ministry of the Environment had not undertaken any in-market surveillance activity, primarily due to a lack of familiarity with the requirements of the Directive. Moreover, the domestic explosives industry in the Netherlands is very small, and consequently the Ministry has not yet accumulated the experience and expertise needed to carry out monitoring activity. It is not thought, however, that products without a CE marking are present in the Netherlands, and that the small size of the industry means that any incidents of non-compliance would quickly become apparent.

In 2007 the Department of Inspection and Enforcement within the Ministry of the Environment launched an annual programme of surveillance, which in 2007 will involve visits to 40 premises where explosives are manufactured, stored or used in order to check that products bear a CE marking and possess the necessary paperwork.

The Intra-Community Transfer of Explosives Document

The authorities in the Netherlands were generally satisfied with the ICTE document and reported that the form had made long-distance transportation of explosives considerably easier for businesses. However, to make the process easier for domestic firms, the Ministry of the Environment had translated and reformatted the document, and also posted it in PDF format on their website. A representative from the Ministry of the Environment was strongly supportive of an online version of the ICTE form that could be completed electronically, in order to simplify the process further. The Ministry of the Environment reported that they receive ICTE forms intermittently, ranging from between two and three a week, to periods where none are received.

Key findings

The main points of note from the case study of the Explosives Directive in the Netherlands are:

- § Domestic legislation governs safety in the explosives industry, but there is presently little in the way of regulation regarding security. New laws coming into force will eventually change this.
- § Domestic production and consumption of explosives in the Netherlands takes place on a very small scale, and consequently the Competent Authority has very little experience of the conformity assessment process. The authorities are content to accept the validity of any CE marked product.
- § There is also very little in the way of in-market surveillance in the Netherlands, primarily since the authorities are not familiar with the requirements of the Directive.

§ The Competent Authority has made some improvements to the ICTE form.

Spain

The explosives industry in Spain

Spain is a major producer and consumer of explosives, particularly within the mining industry. The largest firm is Maxam Corp (formerly UEE) that employs over 1,000 people and manufactures explosives, propellants and associated products (detonators etc).

The wider legislative environment in Spain

The explosives industry in Spain is relatively tightly regulated, with a number of other pieces of legislation in place alongside the Explosives Directive.

Safety

In Spain a licence is required in order to manufacture, store, transport, sell and use explosives. Licences are administered by the national Ministry of Industry, Tourism and Trade (the Competent Authority for explosives). Safety is a major consideration within the granting of a licence to a business, and all applicants are expected to meet national standards governing the likes of safety risks, air pollution and the safety of detonators. Anybody wishing to import explosives into Spain has to register with the Official Registry (*Registro de Explosivos*). As part of this process, documentation including Spanish tax returns, proof of financial capacity and resources to distribute the imported products, and the requisite licences governing storage and distribution are required. Importers are also expected to hold a Civil Responsibility Insurance Policy (*Póliza de Segura de Responsabilidad Civil*) worth a minimum of €300,000 and valid for a year.

Security

National legislation governing security and explosives is very strict in Spain, and in fact is widely considered to be the strictest in the EU. Regulations have been developed in response to the terrorist threat posed by ETA, and more recently by Islamic terrorists following the Madrid train bombings of March 2004. There is concern amongst the Spanish authorities that these standards are much higher than those in place in other EU countries. In the past ETA have used explosives stolen from France (where security requirements were historically less strict), though there has recently been a considerable tightening of national law in a number of countries.

The most relevant piece of legislation regarding security in Spain is the 1998 Royal Decree of Explosive Regulations that was amended twice in 2005. This law includes a number of requirements governing security at all premises where explosives are manufactured, stored or used, and also during transit. Specifically:

- § A licence to manufacture, store, use or transport explosives is dependent upon there being adequate security measures in place.
- § Armed guards are mandatory at all premises (manufacturing, storage, and mines/ quarries), and also during the transportation of explosives.
- § For commercial storage facilities, companies may choose to install video surveillance and an alarm system in place of an armed guard, but only if prior permission is obtained from the Civil Guard.

- § During the transportation by truck of certain volumes of explosives, camouflaged security cars must be present in front of and behind the vehicle.
- § Furthermore, in all activities involving explosives (manufacturing, storage, transport, and usage), firms must fill out a formal Security Plan (*Plan de Seguridad*), which must be approved by the Civil Guard.

Technical security requirements are also set out in the Ministerial Agenda of 1997 (*Orden Ministerial de 23 de Abril de 1997*). This document sets out specifics such as the exact physical and electronic security requirements for storage facilities (for instance the number of guards per square metre, the extra surveillance requirements for larger facilities), and also the types of electronic surveillance equipment that are allowed as a substitute or supplement for armed guards.

The application and implementation of the Explosives Directive in Spain

The Competent Authority responsible for the implementation of the Explosives Directive in Spain is the Ministry of Industry, Tourism and Trade. Within the Ministry there is a sub-division of the Area of Explosives responsible for in-market surveillance and conformity checks.

Conformity assessments and the Notified Body

The Ministry of Industry, Tourism and Trade reported that they always accept the validity of a CE marking, regardless of which Notified Body had carried out the conformity assessment, since it was understood that the Explosives Directive forbids discrimination on the grounds of the origin of the test. However, a representative from the Competent Authority expressed concern about the nature of the conformity assessments carried out in certain Member States. These anxieties primarily stem from the approaches adopted by certain Notified Bodies towards the conformity assessments, and whether this affects the overall safety of the product. In particular, doubts were expressed where a CE marking is awarded on the basis of tests carried out by manufacturers, or sub-contracted to third parties. Unlike Notified Bodies in the UK, France and Germany, the Spanish Notified Body insists on carrying out each and every test on a product, and will not accept any results from an external body (such as the manufacturer of the product).

The Notified Body in Spain is the *Laboratorio Oficial José María de Madariaga* (LOM) that is based at the Technical School of Mining and Engineering at the Polytechnic University of Madrid (*Universidad Politécnica de Madrid*). The purpose of LOM was set out in the Royal Decree 334/1992, under which the organisation is designated as the responsible body in Spain for the testing, certification and investigation of a wide range of mining and industrial activities. The following table shows the number of Module B, C and D tests carried out by LOM between 2003 and 2006 (data on the number of tests failed are not available, but it is thought that this is a very rare event). It is thought that LOM tested around 500 different products between 1997 and 2007.

Year	Number of Module B tests carried out	Number of Module C tests carried out	Number of Module D tests carried out
2006	2	1	2
2005	2	0	2
2005	39	0	6
2004	33	0	5

2003	2	0	2
All years	78	1	17

Source: Laboratorio Oficial José Maria de Madariaga

Ongoing quality control of the Notified Body

The Competent Authority and Notified Body work together closely in the implementation of the Directive, and communications between the two organisations are reported to be good. There is, however, no formal system through which the Ministry of Industry, Tourism and Trade monitors LOM, beyond regular meetings to discuss trends and any problems with the conformity assessment process.

A representative from the Notified Body also reported that they regularly attend meetings with the other Notified Bodies, during which time concerns or issues with conformity assessments are identified and discussed. Though this has been seen as adequate quality control by some Member States, the Spanish authorities reported that they see a greater need to monitor conformity testing, particularly where Notified Bodies which are subcontracting tests or accepting the assessments of manufacturers.

In-market product surveillance

In Spain, in-market product surveillance is the joint responsibility of the Competent Authority and the Notified Body. Products are checked to ensure that they comply with the requirements of the Explosives Directive throughout the supply chain, from production facilities through to sites where explosives are used. Unfortunately it has not been possible to obtain information on the scale of this activity, though the authorities reported that, in combination with the administrative requirements associated with explosives, they were confident that surveillance was thorough enough to identify any cases of non-compliance. In fact, the Ministry of Industry, Tourism and Trade reported that there had not been a single case in recent years where a product had been found on the market that did not comply with the Directive.

The Intra-Community Transfer of Explosives Document

In Spain the ICTE form is administered and expedited by the Civil Guard. Representatives reported that the document works well, though it took a long time to become part of the Directive. In some cases it was thought that certain Member States do not approve forms with sufficient speed, thus causing delays to businesses.

Key findings

The main points of note from the case study of the Explosives Directive in Spain are:

- § National regulation in Spain governing safety and – in particular – security in the explosives industry is very strict. There are several administrative and regulatory requirements that anybody wishing to manufacture, store, transport or use explosives in Spain must meet, thus imposing considerable additional operational costs in comparison to most other EU countries.
- § On a related note, the Spanish authorities are strongly supportive of the development of minimum security standards for use in the industry throughout the EU, in order to tighten requirements in other Member States.
- § Though the Spanish authorities stress that they have never rejected the validity of a CE marked product, they nonetheless have concerns about the approaches

taken by a number of Notified Bodies, and thus the overall safety of the products that they test.

- § In-market surveillance of explosives products in Spain is reported by the authorities to be thorough, though it has not been possible to obtain any facts regarding the scale and nature of such checks.

The UK

The explosives industry in the UK

The UK is one of the largest consumers of explosives in the EU. A large proportion of these explosives are imported (from within the EU and the US), and the domestic explosives production industry is relatively small. Key firms include Exchem Explosives Ltd and Ulster Industrial Explosives Ltd.

The wider legislative environment in the UK

In addition to the Explosives Directive there are other pieces of domestic legislation governing safety and security in the explosives industry.

Safety

In the UK, a licence is required in order to manufacture or store explosives. Depending on the quantity of the explosives, this licence is granted either by local government, or by the national Health and Safety Executive. The Explosives Act of 1875 (recently updated) includes a number of safety requirements in relation to the manufacture and storage of explosives, covering issues such as the minimum distance between the site in question and inhabited buildings, and the safe disposal of explosives. Businesses manufacturing or storing explosives are required to take measures to prevent explosions, and to provide protection in the event of an explosion.

Security

Security arrangements for explosives in the UK are amongst the strictest in the EU – a legacy of the historical problems with domestic terrorism. In the 1990s there was a national upgrading of security arrangements at sites where explosives were manufactured or stored that tightened requirements considerably. Anybody wishing to acquire or keep explosives must obtain an Explosives Certificate from the local police force, who will undertake a background check on the applicant to determine their suitability. Premises where explosives are manufactured or stored must also meet a number of security related criteria, though these do vary in detail between police forces. At a minimum, however, facilities must be kept locked, and should also include an alarm system that is capable of alerting the organisation responsible for security at the site (such as a private security firm). The Health and Safety Executive has also issued guidance on recommended security arrangements for the storage of Ammonium Nitrate.

The application and implementation of the Explosives Directive in the UK

The Competent Authority responsible for the implementation of the Explosives Directive in the UK is the Health and Safety Executive.

Conformity assessments and the Notified Body

The Health and Safety Executive reported that they do not question the validity of any CE marking on a product, regardless of which Notified Body was responsible for the conformity assessment. However, representatives from the Health and Safety Executive accepted that this is not the case throughout the EU, and that they are aware of authorities requiring additional tests on CE marked products, though they

could not provide any examples. It was thought that Notified Bodies in smaller countries where conformity assessments were required infrequently might not have the necessary experience or expertise to complete tests as thoroughly as Notified Bodies in Germany or France. In these cases problems could arise, and authorities in other EU countries may be less willing to accept the CE marking awarded by the Notified Body.

The Notified Body in the UK is the Health and Safety Laboratory, an independent facility that carries out research into a range of product safety issues, with a focus on explosives and pyrotechnics. The Health and Safety Laboratory reported that almost all of their conformity assessments consist of Module D tests, involving approval of applicant's quality assurance systems rather than individual products. However, data were only available on the number of Module C tests carried out in the past three years:

Year	Number of Module C tests carried out	Number of Module C tests failed
2006	0	0
2005	5	0
2005	2	0
<i>All years</i>	<i>7</i>	<i>0</i>

Source: Health and Safety Laboratory

The Health and Safety Laboratory has adopted a slightly different approach than other Notified Bodies to product conformity assessments. Provided an applicant has passed a Module B assessment (which concerns the nature of a firm's production and quality assurance systems), then the Health and Safety Laboratory will accept the results of some of the applicant's own product safety tests. This approach is employed in order to save time and money, since it reduces the amount of testing that the Notified Body has to carry out on the product. The Health and Safety Laboratory stressed that this approach is perfectly acceptable within the guidance issued by CEN, and that manufacturers will always carry out exhaustive tests of their own.

Businesses who reported that they had employed the Health and Safety Laboratory in order to carry out conformity assessments were favourable to this approach. One respondent to the business survey noted that the Health and Safety Laboratory is consequently able to carry out tests relatively quickly. A comparable assessment took the Health and Safety Laboratory one month, whereas the German Notified Body took six months.

Ongoing quality control of the Notified Body

There is no formal system through which the Health and Safety Executive monitors the activity of the Health and Safety Laboratory, though there is regular communication between the two organisations. Moreover, the Chief Inspector of Explosives from within the Health and Safety Executive sites on the Health and Safety Laboratory Management Board. The Health and Safety Laboratory stressed that quality control also tends to take place on a formal and informal basis between the Notified Bodies. All Notified Bodies in the EU meet once a year to discuss the conformity assessment process and trends in the explosives industry as a whole. Any issues with individual Notified Bodies would become clear at this point. A representative from the Health and

Safety Laboratory also reported that they had spent time with the Romanian Notified Body in order to share good practice and work towards improving quality standards.

In-market product surveillance

In-market surveillance is the responsibility of the Explosives Inspectorate within the Health and Safety Executive. Inspectors from the Health and Safety Executive periodically visit premises where explosives are manufactured, stored or used on a large scale. These checks cover a wide range of issues, including whether products comply with the Explosives Directive (hence bear a CE marking and have the necessary paperwork), and also whether they meet the requirements of domestic legislation (in respect of safety and security).

The scale of this inspection activity is thought to be sufficient, and the authorities are content that the importers and manufacturers of explosives products comply with the regulations governing the industry. It is not thought that there have been any instances in the past few years where a product has been found on the market that did not comply with the Explosives Directive. The explosives industry in the UK is relatively small and so it is possible for the Health and Safety Executive to maintain informal contacts with the major firms in the country.

The Intra-Community Transfer of Explosives Document

The ICTE form is generally thought to be working well, and has simplified the process of transporting explosives across borders in the EU, whilst maintaining surveillance and monitoring systems. It was noted, however, that there are differences in the ways in which the ICTE form is applied. In Northern EU states (such as the UK), ICTE forms are approved for the transport of explosives within a set time period, regardless of how many movements are made. In Southern EU states (including France and Spain), the businesses must complete a separate form for each and every product transfer, thus adding a considerable cost to the process.

Key findings

The main points of note from the UK case study are:

- § Safety and security in the explosives industry are regulated by national legislation. Security requirements are amongst the strictest in the EU;
- § The authorities always accept the validity of a CE marking, regardless of where the product has been tested;
- § The Notified Body in the UK has adopted a different approach to conformity assessments that involves making use of the results of manufacturers' tests. The overall process is thus considerably speedier than it is in many other Notified Bodies.
- § In-market surveillance takes place on a relatively modest scale, though a non-compliant product has never been discovered on the UK market.

ANNEX 6: THE COUNTERFACTUAL

The Study Specification issued by DG Enterprise and Industry required that the evaluation assess the counterfactual for the Explosives Directive; that is, whether the same effects could have been achieved in the absence of the Directive and through means other than EU legislation. Since the Directive was adopted in 1993 this is a somewhat challenging exercise. A considerable period of time has elapsed since the introduction of the Directive, meaning that very few stakeholders would be able to accurately assess how events would have unfolded in the absence of the legislative instrument. Moreover there is no baseline to compare with, since there is no published material available on the situation at the time of the introduction of the Directive.

It is difficult to see how the Single Market in explosives could have been created in any other way than EU legislation. It might have been possible for Member States to align their national standards independently, but this would be a highly technical exercise, and would have been unlikely to extend across all 27 Member States. Harmonised standards are critical to the operation of the Single Market; without these the costs to producers of complying with varying national laws would have been considerable (though without baseline data from 1993 it is not possible to quantify this), and thus the prices of explosives would presumably be higher. The example of the ICTE form highlights the fact it is very difficult to create a harmonised system between Member States without the involvement of the EU, despite there being a clear need for harmonisation.

The same applies regarding safety in the explosives industry. It is unlikely that all 27 Member States could agree common safety standards for explosives products. Some countries would doubtless insist on very strict standards, and indeed consultees in Germany and France noted that the introduction of the Directive did little to raise product safety standards in their countries which were already set at a high level. In other countries – particularly a number of the recent accession states – the Directive did improve safety standards, and the major benefit of EU legislation is that it harmonises safety across the Community. Whilst in some countries the counterfactual might be very similar to the current situation, in many others those working in the explosives industry would have been exposed to a much greater degree of risk. Again, without historical data, however, it is not possible to quantify these differences.

Safety and security highlight the variations between Member States in areas not directly covered by the Explosives Directive. Safety standards do differ slightly between countries – albeit in relatively minor ways – but security standards are very different across the Community. Varying standards are a cross-border issue and affect security in all Member States (the example of ETA in France and Spain highlights this), and also impact on the Single Market, since national legislation governing security can impose additional costs on businesses. The problem is such that there is widespread support amongst the Competent Authorities consulted as part of this study for minimum EU security standards.

Finally, it is possible that the Directive could have been designed to be more similar to the 'old approach'. Under such a system, responsibility for developing the technical details of the conformity assessments would lie with the European Commission, rather

than CEN. The text of the Directive would then have contained detailed technical specifications which would have to have been transposed into national law. The additional workload for regulators, together with the associated delays, means that this system has many disadvantages, and it is hard to identify ways in which the effectiveness of the Directive would have been improved.